“MORBIDITY PATTERN AMONG WOMEN DURING PUERPERIUM AND ITS RISK FACTORS – A CONCURRENT COHORT STUDY”

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT OF THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY, CHENNAI, FOR THE DEGREE OF MD BRANCH XV (COMMUNITY MEDICINE) EXAMINATION TO BE HELD IN MAY 2018

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CERTIFICATE

This is to certify that "Morbidity pattern among women during puerperium and its risk factors – A Concurrent Cohort Study" is a bona fide work of Dr. Anjali Sriramanarayanan Nair in partial fulfilment of the requirements for the M.D Community Medicine examination (Branch-XV) of the Tamil Nadu Dr. M.G.R. Medical University, Chennai, to be held in May 2018.

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I have independently reviewed the literature, collected the data and carried out the evaluation towards the completion of the thesis.

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http://niti.gov.in/content/maternal-mortality-ratio-mmr-100000-live-births
http://www.who.int/sdg/targets/en/
http://apps.who.int/iris/bitstream/10665/97603/1/9789241506649_eng.pdf
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http://www.censusindia.net/
http://www.who.int/bulletin/volumes/95/10/17-192237/en/
http://www.who.int/reproductivehealth/news/antenatal-care/en/

Instances where selected sources appear:

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Glossary of Abbreviations

CDC- Center for Disease Control

CHAD- Community Health and Development

CMC- Christian Medical College

DALY- Disability Adjusted Life Years

DSM- Diagnostic and Statistical Manual

PHC- Primary Health Centre

PHN- Public Health Nurse

PNC- Postnatal Care

PTCHW- Part Time Community Health Worker

NFHS-National Family Health Survey

UTI- Urinary Tract Infection

WHO- World Health Organization

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1 Introduction

Postpartum period also known as puerperium is the period up to 6 weeks (42 days) after childbirth and is a crucial period for ensuring the health and survival of a woman and her newborn. Routine post-partum care is integral to ensuring holistic maternal care and is still largely neglected. This period poses a special challenge in providing good quality care to both the mother and child. Suitable measures during puerperium can have a positive impact in enhancing the health of women. However, lack of care during this period can have a huge impact in the form of disability or death to both.

Currently in India, the postpartum checkup for the mother is limited to vaginal examination and contraceptive education. In a national survey it was found that around one third of mothers who received postpartum care, were of the opinion that their felt needs were unaddressed. Women were interested about the diet to be followed, exercise to be done in order to gain back original body size, ways of tackling fatigue and resuming normal activities apart from child care information.

The maternal health status is assessed by indicators during each of the antepartum, peripartum and postpartum periods. The most important among them is the maternal mortality ratio. Globally India ranks 53rd among 182 countries for having the highest maternal mortality ratio.(1)Maternal death is the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.(2) Maternal mortality ratio is calculated as number of maternal deaths per 100,000 live births during a given

period. As of 2013, maternal mortality ratio in India was found to be 167 per 100,000 live births.(3)99% of maternal deaths occur in developing countries and there is a large disparity in maternal mortality among developed and developing countries. A systematic analysis of the various studies assessing the causes of maternal death globally between 2003-2012 showed that hemorrhage accounted for 27.1%of deaths hypertensive disorders for 14%, sepsis for 10.7%, abortion for 7.9%, embolism for 3.2% and all other direct causes for 9.6% of maternal deaths.(4) A similar distribution was seen in the national representative survey for the causes of maternal death from 2001-2003 with hemorrhage contributing to 27%, sepsis to 17%, abortion to 10%, hypertensive disorders of pregnancy to 7%,indirect causes to 16% and other causes to 23% of maternal deaths.(5)

The issue of the alarming rise in maternal mortality rates globally was discussed first in 1987. Since then, many initiatives have been taken to reduce the burden worldwide. The safe motherhood initiative was among the first to be established after which this issue was taken up in the International conference on population and development as well as fourth world conference on women. The millennium development goals were established in the year 2000 which aimed at reducing maternal mortality by 75% by the year 2015. (6) This is now currently followed by the Sustainable development goals which aims at reducing the global maternal mortality ratio to less than 70 per 1,00,000 live births.(7)

The burden of maternal illness in a large part is contributed by morbidity experienced by postpartum women. The standard for postpartum care recommended by WHO is at least three postnatal contacts after the first 24 hours of birth. All mothers and

newborns are expected to be seen by a health care worker on day 3 (48- 72 hours) , between 7-14 days after birth and six weeks after birth .(8)There are national indicators to assess for the quality of postpartum care . The standards include a visit within 48 hours of delivery. However, in India, the proportion of women who received a postpartum visit within 48 hours irrespective of their place of delivery was 67.2%. A multilevel analysis performed in 9 states of India assessing the factors associated with maternal healthcare service utilization revealed that women with a birth order of 3 and above, lower education level and lower socioeconomic status were less likely to utilize postnatal care services. At the community and district levels, type of residence, average population covered per PHC, availability of PHC with labour room facility and percentage of registered pregnancies were significantly associated with the utilization of PNC services.(9) Postpartum visits to the mother as recommended by WHO helps the health workers assess the physical and psychosocial wellbeing of the mother. However currently there are no concrete national strategies in place to ensure optimum postpartum health. Maternal morbidity especially during the postpartum period is still difficult to measure. More studies are required to look at the relationship between different types of morbidity and their potentially adverse health consequences.

2 Justification

Maternal morbidity is defined as any illness or injury caused by, aggravated by or associated with pregnancy or an additional of childbirth.(10) In 1993 WHO estimated that around 42% of women among the 129 million who gave birth annually experienced at least mild complications of pregnancy and around 15 million women among them develop pregnancy related complications with long term effects. In addition to the acute complications, health during pregnancy and childbirth has a further impact on health and wellbeing of the family and can lead to adverse situations like broken families, divorce, isolation etc. Mental health problems of women apart from family instability and loss of community status has possible effects have been reported. Such studies have shown that the loss is not easily quantified and hence an area that needs to focused upon. Majority of the adverse effects experienced by the woman and her family due to morbidity arising from pregnancy and childbirth are preventable if identified early. This will benefit them and reduce the illness burden on the healthcare system. Cash incentive schemes like Janani suraksha yojana have definitely improved the institutional care received by the woman through her pregnancy and after but there is still a long way to go.

Currently in the United Kingdom, routine surveillance systems to assess uncommon but severe pregnancy complications nationally based on the WHO near miss approach which has 25 severe markers for maternal morbidity is in use. The success of this initiative has now encouraged other countries like New Zealand, Australia and several other European countries to establish similar systems. (9)(11)This study is a

community based initiative to identify such potential morbidity and its interrelated socioeconomic and obstetric risk factors. Results from similar studies across the country would further help in developing a strategy relevant to the Indian context of identifying women who develop morbidity and potential near misses. Such a strategy will also help us identify women who are at risk and hence make targeted interventions towards them.

3 Aim and Objectives

3.1 Aim

To study the morbidity profile among women in postnatal period up to 6 weeks after childbirth and to determine risk factors for the identified morbidity.

3.2 Objective

1. To determine the magnitude of morbidity experienced among women in postpartum period up to 6 weeks after childbirth in a rural bock of southern India.
2. To find the association of demographic and obstetric risk factors with the morbidity

4 Literature review

4.1 Introduction

Maternal morbidity among women after childbirth varies from minor to very severe illnesses. Fatigue, headache, backache, constipation and sexual problems are the typical symptoms during this period. However postpartum hemorrhage, infections like urinary tract infection, mastitis, infection at surgical wound site, puerperal sepsis, infection at episiotomy site, anemia, depression, other complications like breast abscess, breast engorgement, uterine prolapse, urinary and fecal incontinence, dyspareunia, hypertension, hemorrhoids, perineal tears, fistula and pulmonary embolism can also develop.(12) Many of these conditions develop during child birth and can be managed at the hospital itself before getting discharged. However, these can manifest among the women who have had a home delivery. The illnesses with the potential of developing after discharge from hospital contribute to a significant proportion and the magnitude depends on the socio-demographic factors like literacy, socioeconomic status etc. A study done in Lusaka, Zambia analyzing the postpartum morbidity requiring hospital admission showed that women are subject to both obstetric morbidity like puerperal sepsis and non-obstetric morbidity like infections such as pneumonia, malaria etc.(13) A cohort study done in Maharashtra, India reported the incidence of maternal obstetric morbidity as 52.6% of which 17.7% was during labour and 42.9% was during puerperium. The common problems encountered during puerperium included breast problems which was 18.4%, puerperal genital infections which was 10.2%, secondary postpartum hemorrhage was 15.2% and insomnia was 7.4%.(14)

The most dominant model in safe motherhood is the ‘3 delay model’. (15) This model is based on the time elapsed from :-

- Onset of symptoms of complications to recognition of the need to visit a health facility,
- Leaving the home to reaching the facility,
- Presentation at the facility to provision of appropriate services.

All of the above possible lapses are dependent on multiple factors such as poverty, education levels, geographical accessibility, adequate functioning of the referral systems, presence of appropriate infrastructure and trained personnel and provision of good quality care at the service centers. The disadvantage of this model is the lack of the possible fourth delay which is the delay to seek care after childbirth once the woman has been discharged from the hospital or after home delivery. Although there has been an improvement in the global attention to maternal mortality due to the increase in number of studies done, we still largely depend on research. Paucity of data on morbidity only worsens the present state. Furthermore, community based data is almost nonexistent.

Investigation of the magnitude of morbidity experienced by women during postpartum period can reduce the gap in knowledge regarding the association of maternal morbidity with various factors. This can ensure that appropriate policies can be made to help reduce its burden.

4.2 Postpartum infections

A significant proportion of maternal deaths occur in postpartum period. A systematic analysis done by WHO showed that pregnancy related infections contributed to 9 % of maternal deaths. during 2003-2009.(16) However, in most of the developing countries the entire focus of the maternal and child health programs shifts on to the neonate after childbirth.

The term postpartum infection refers to the various bacterial infections that occur during the first 6 weeks after childbirth. Common postpartum infections include endometritis or puerperal sepsis, postsurgical wound infections, mastitis, urinary tract infections and respiratory complications from anesthesia. Premature rupture of membranes, history of caesarean delivery, frequent vaginal examinations are the most common risk factors for developing postpartum infections. Moreover, presence of diabetes, obesity and pre-existing pelvic infection predisposes a woman to a higher risk of infection postpartum.(17) Most studies tend to underestimate the incidence of infections in the postpartum period . This is primarily because most of the identified episodes are self-reported. The estimate of deaths due to infections are based on verbal autopsies. In reality the larger proportion of infections during postpartum period remain unidentified and unreported. According to a national study of the causes of maternal mortality from 2001-2003, 16% of women died during that period due to pregnancy related infection.(18)Infections contribute significantly to the burden of illness in the post-partum period , and are entirely preventable. Our study aims at estimating the magnitude and to study the relationship between determinants and puerperal infections so that appropriate measures can be taken to

help reduce infections in postpartum period paving the way to a better quality of life to the mother and her baby.

4.2.1 Urinary Tract Infection

Urinary tract infections are the most common bacterial infection affecting pregnant women. It generally presents as either asymptomatic bacteriuria, acute cystitis or acute pyelonephritis. Among them, acute pyelonephritis is the one that is most associated with morbidity to the mother and fetus. Asymptomatic bacteriuria occurs in 2 to 7 percent of pregnant women.(19)Pregnant women are at a risk for urinary infection starting from 6 weeks and peaking during 22- 24 weeks of gestation.(20) Screening during antenatal period for urinary infection is not routinely done. Factors associated with a higher risk of bacteriuria include a history of prior urinary tract infection, pre-existing diabetes mellitus, increased parity, and low socioeconomic status.(21)

Urinary tract infection in pregnancy can lead to serious consequences in both the mother and the growing fetus. Once the mother develops a urinary infection she is more prone to have a premature delivery, develop chorioamnionitis and complications like hypertension or preeclampsia and anemia. The neonate of a mother infected with urinary infection is more prone to infections like pneumonia and sepsis ,low birth weight and prematurity.(20) Instrumentation, catheterization and surgical procedures during delivery increases her risk of urinary tract infection in the postpartum period. A case control study done in Washington identified as having

a caesarean section, tocolysis and being induced for labour as risk factors for developing urinary tract infection postpartum.(19)

Through this study we aim to identify the proportion of urinary tract infection among the other infections seen in women postpartum.

4.2.2 Mastitis

Breast milk is the best source of nutrition for babies before they are able to digest other semi solid foods. WHO recommends exclusive breast feeds for infants up to 6 months of age followed by complementary feeds alongside breast milk thereafter in order to achieve optimal growth and development and to prevent common childhood illnesses.(19) In spite of the many advantages of breast milk, the proportion of infants who are exclusively breast fed is far from acceptable levels. NFHS 4 (2015- 2016) data suggests that only 57.2% of babies aged 0- 6months are exclusively breast fed indicating that we need to still focus on the importance of breast feeding and work towards achieving optimal goals.(22) One of the common problems women face is the development of breast related infections which hinder them from breast feeding and therefore resorting to commercially available milk products for the infant's nutrition.

Mastitis is an inflammatory condition of the breast which may or may not be associated with infection. However, when associated with infection the most common causative organism is Staphylococcus aureus. It almost always occurs during lactational period and hence is also known as lactational mastitis. WHO estimates that about 10% of breastfeeding mothers worldwide develop mastitis, though

incidence may vary between 2.6% and 33%.(21) It typically presents as firm, red, tender, swollen area of one breast associated with fever in a nursing mother. Systemic complaints may include myalgia, chills and flu like symptoms.(20)The pain can be debilitating for the feeding mother causing her to discontinue breast feeding prematurely. If inadequately managed it can lead to complications like breast engorgement, breast abscess or even inflammatory breast cancer.(20) The most common causes of lactational mastitis are milk stasis and underlying infection. Milk stasis occurs if the mother is unable to feed for reasons such as illness, stress, fatigue or practices inadequate breast feeding techniques with delayed timings or has problems in the nipples like sore nipples or plugged ducts. Many a times women are wrongly advised by health workers to discontinue breast feeding once mastitis develops which has only led to further worsening of the condition. Mastitis occurs mostly during the first 12 weeks after delivery. In a study done in Glasgow, 18 % of the women experienced postpartum at least one episode of mastitis with almost 53% of them in the first four weeks.(23) A multi-centric cross sectional study done across three hospitals in Cameroon identified poor breast hygiene, less number of feeds in a day, poor awareness of breast feeding techniques and ample supply of milk possibly due to voluntary discontinuation of breast feeding before completion of 6 months as recommended by WHO as the predictors for development of mastitis in postpartum period.(21)

4.2.3 Wound infection

With an alarming increase in the rates of caesarean sections and episiotomy procedures in both the developed and developing worlds, the proportion of women developing postpartum wound infection has shown a rising trend. Postpartum wound infections which include incision site of caesarean section, episiotomy incision site, tear and laceration contribute to a significant morbidity and at times can progress into sepsis and turn out to be fatal. It has led to prolonged hospital stay after delivery posing a risk to both the mother and infant leading to increased burden on the health care system. Most of the research focuses only on infections arising from post caesarean section and episiotomy and the tears and lacerations go unaccounted for. It commonly presents with increasing pain, discharge, edema, localized erythema and tenderness along with occasional systemic symptoms of infection.

WHO recommends that no more than 10-15% of births should be by caesarean section.(24) In 2014 caesarean section rates were analyzed in 150 countries and a 18.6% of births were by caesarean section.(25) A case control study in Brazil reported an post caesarean section infection rate of 1.44%.(24) Another hospital based study done in south India found the prevalence of post caesarean section wound infection to be 4.1%.(26) Studies have shown that pregnancy related factors like hypertensive disorder, gestational diabetes mellitus, twin pregnancy, preterm rupture of membranes, greater number of vaginal examinations, prolonged trial of labour prior to surgery, use of epidural analgesia, use of internal fetal monitoring and chorioamnionitis are risk factors for developing infection. Performing caesarean section in an emergency setting, lack of prophylactic antibiotics, blood transfusion,

caesarean hysterectomy and longer duration of surgical procedures are risk factors for developing infection.(27)

Episiotomy is a surgical incision made in the perineum during the second stage of labour to expand the vaginal opening when hastening vaginal delivery of the baby is warranted. Previously it was routinely in use and had increased complications. Hence it was recommended to perform it on an individualized basis.

The incidence of infections varies worldwide. Women seek treatment from multiple care providers making it difficult to obtain information from different sources. Furthermore, the follow up may be incomplete since most of the women are discharged from the hospital early. Finally, there is a huge variability in the environment in which maternity care is provided globally and high infection rates can be attributed to poor hygiene, lack of adequate health care, and poverty. The Royal College of obstetricians and gynecologists and the national institute of health and clinical excellence have recommended guidelines to be followed by health professionals during intra-partum and postpartum care. Methods of identifying signs of infection and maternal education on perineal hygiene, diet and pelvic floor exercises have also been highlighted. A study done in the United states suggested that one in ten women who sustained a perineal tear at vaginal delivery that required suturing developed perineal wound infection with instrumental deliveries and prolonged rupture of membranes predisposing women to it.(28) This study aims to highlight the need for post discharge surveillance based programs to prevent and actively manage infections among women having a surgical wound attained during process of childbirth.

4.2.4 Puerperal Sepsis

Puerperal sepsis is defined as infection of the genital tract occurring any time between the rupture of membranes or labour, and the 42nd day postpartum. The diagnosis is made in the presence of 2 or more of the following clinical signs and symptoms namely pelvic pain, fever, abnormal vaginal discharge with foul odour and delay in the rate of reduction of the size of the uterus.(29) In spite of the surge in antibiotic prophylaxis, puerperal sepsis is still currently widely present in developing countries and can eventually lead to shock or even death. It usually occurs 24 hours after delivery, is largely undiagnosed and unreported due to the poor postpartum follow up.(29) According to Global burden of disease 1990, maternal sepsis ranked 46th in terms of DALY's and attributed for 18% of the total burden of conditions and 15% of all maternal deaths.(29) Studies have shown prolonged labour, frequent vaginal examinations in labour and premature rupture of membranes to be strong predictors of developing postpartum sepsis. However, there are many other factors such as delivery being conducted by an untrained birth attendant, inaccessibility of health facilities, long distances to travel in labour, low socioeconomic status, lack of adequate hygiene, unavailability of postpartum care, illiteracy, poor support and lack of awareness of symptoms and signs of puerperal sepsis which also indirectly contribute to the increasing burden. In a study done in Delhi, the incidence of puerperal sepsis was 2.5% over a 4 year follow up period.(30) In India, many health facilities lack the basic infrastructure and are staffed by untrained professionals handling the delivery and surgeries, and consequent poor practice of safe surgical skills, lack of trained personnel in peripheral units of healthcare could contribute to

the rise in number of women affected by puerperal sepsis. A lack of awareness among women about contraceptive measures leading to higher proportions of unwanted pregnancy and hence unsafe abortion methods could lead to increased infections. Unnecessary delay in diagnosis due to shortcomings in the established health system such as poorly functioning laboratories, wrong practice of overprescribing antibiotics and hence leading to resistance could contribute to the rising infections.

The need of the hour is community based studies to help identify such at risk women and aggressive measures to educate women of such occurrences during antepartum period itself. This will also help develop better institutional protocols which will in turn be instrumental in planning preventive strategies at higher levels.

4.3 Postpartum Anaemia

Anaemia refers to a low concentration of haemoglobin in the body. The oxygen carrying capacity is insufficient to meet the physiologic needs which may vary by age, sex, altitude, pregnancy status etc. The pathophysiology of anaemia is quite diverse and it most typically presents as generalized fatigue, light headedness, palpitations or shortness of breath. Anaemia is considered to be one of the most debilitating nutritional deficiencies that is often undertreated and its burden underestimated. In India, inadequate iron and folate levels either due to poor dietary intake or poor bioavailability and chronic blood loss during infections like malaria and hookworm infestations have been stated as the causes for anaemia.(31) Among the various types, iron deficiency anaemia is the most common with women and children being more vulnerable and has a high prevalence in the developed world as well unlike other nutritional deficiencies.

A study done in 2013 which estimated the global burden of anaemia from 1990- 2013 identified that 27% of the world's population had anaemia with developing countries bearing more than 89 % of the burden. Women of the reproductive age group and pre-school children were at the highest risk of developing the disease as per the study.(32) According to NFHS 3 statistics (2005-2006), 59 % of pregnant women in India are anaemic.(33) Anaemia is said to directly cause around 20% of the maternal deaths and indirectly cause another 20% of maternal deaths in India.(34) Apart from its contribution to maternal mortality, anaemia in pregnancy is also known to be associated with preterm labour, fetal growth restriction, low birth weight and infant mortality. It also impairs the lactation and causes postpartum depression and poor maternal/infant interactions.(35) Infants of mothers who are anaemic are prone to develop anaemia as well in their growing years making them more susceptible to developmental delay and infections. WHO has given cut off Haemoglobin values for various age and gender groups below which anaemia is diagnosed, the values of which are mentioned in the table below.(36)

Table 4.3.1 WHO Haemoglobin Cut-off Values

Age or gender group	Haemoglobin value
Children 6-59 months	11.0
Children 5-11 years	11.5
Children 12-14 years	12.0
Non pregnant women (above 15 years of age)	12.0
Pregnant women	11.0
Men (above 15 years of age)	13.0

In India, the Ministry of health and family welfare has implemented supplementation strategies apart from diet diversification and food fortification techniques to combat the growing burden of anaemia. All pregnant and lactating women are given 100 mg of elemental iron and 500 mcg of folic acid for a minimum of 100 days during both pregnancy and postpartum.(37) Blood loss during delivery poses an important risk to developing postpartum anaemia. The postpartum phase is a critical period for a woman and her newborn. The presence of anaemia decreases the quality of life and delays her ability to resume daily activities.

Studies show that almost 82-88% of deaths occurred within first 2 weeks after delivery of which the first 24 hours was the most crucial time.(38) A community based study in Rajasthan identified anaemia as the most common morbidity during postpartum period with 7.4% of women suffering from severe anaemia and 46% from moderate anaemia.(39) Anaemia during postpartum period can contribute to low milk supply, delayed wound healing, low immunity and increased susceptibility to infections.(40) (41) Studies have shown antenatal anaemia as the single most important risk factor for developing postpartum anaemia.(42) In addition to this, a study done in South India showed that lower maternal age, poor compliance to supplementation, perceived higher blood loss and presence of anaemia at 36 weeks of gestation are risk factors for developing postpartum anaemia.(43) Another study done in Mangalore, South India described illiteracy of mothers, parity of 3 and more and inter-pregnancy interval of less than 3 years as contributing factors for postpartum anaemia.(44) Antenatal anaemia is actively screened for and appropriate

measures are taken to reduce its burden. However postpartum anaemia is not routinely screened for and its burden underestimated.

The objective of this study is to determine the prevalence of postpartum anaemia and its determinants among women of a rural block so that a focused approach towards reducing its burden can be planned alongside other targeted interventions to enhance quality of life in the postpartum period of a woman.

4.4 Postpartum depression

Postpartum period has been a time of increased risk for developing serious mood disorders. Despite the launch of the national mental health program in 1982, mental health problems of a woman during her pregnancy and postpartum period has not been given much attention. A lack of training of health workers to screen and assess these conditions during their routine care has only elevated their burden. Unfortunately, mental illness affecting a woman during peripartum and postpartum period is not taken into consideration much during the overall maternal mortality and morbidity assessment of the country. Hence there is currently no active screening tool in use to determine the burden of mental illness in the community. There is very limited availability of mental health specialists in the country and utilization of the existing services is also very poor mainly due to the stigma associated with it. However, the number of studies done across the country has increased in the last decade which suggests that maternal mental illness is being considered as a significant illness.

Postpartum affective illness comprises of postpartum blues, postpartum depression and postpartum psychosis. Postpartum blues also known as baby blues or maternity blues. It is the most commonly observed mood disturbance during puerperium with symptoms beginning within a few days and can persist up to several days after delivery. Studies have shown that the prevalence of postpartum blues ranges from 30-75%.(45) Its symptoms include brief crying spells, irritability, nervousness, poor sleep and emotional reactivity.(46) It is generally a mild form of the illness and requires only reassurance. However up to 20 % of these women will develop major depression in the first postpartum year.(45) The second component among the affective illness is postpartum depression which lasts for a longer time. As per DSM – IV criteria an episode of major depression after delivery is defined as two weeks or more of persistent depressed mood or loss of interest in daily activities plus any four associated symptoms like fatigue, feeling of worthlessness or inappropriate guilt, poor concentration, suicidal ideation, sleep disturbance, loss of appetite, psychomotor agitation or slowing that onset within 4 weeks after childbirth.(46) A meta-analysis of studies done on postpartum depression in India revealed that the overall prevalence of postpartum depression among Indian mothers was 22%.(47) The risk factors identified consistently among the various studies included presence of recent stressful life events, previous history and antenatal history of depression, financial difficulties and poor social support. Factors such as stress related to care of the child and low self-esteem were moderate predictors and poor relationship with partner, lower socioeconomic status, single parent and presence of any complications during pregnancy and delivery were low risk predictors of postpartum depression**.** A

community based study done in South India identified problems with in- laws and birth of a female child when a son was desired as contributory factors to postpartum depression.(48) On the other hand being satisfied with the pregnancy, being multiparous and perceived adequate support from family and friends were associated with a decreased likelihood of depression based on a study done in South Asia.(49) The third and the most serious component of postpartum affective illness is postpartum psychosis. It presents with rapid onset of symptoms presenting as early as first 48 to 72 hours postpartum with the majority of these episodes developing within the first 2 weeks after delivery.(50) Symptoms include typically depressed or elated mood, disorganized behavior, mood lability, delusions and hallucinations.(50) Mothers who have developed depression or psychosis are at a risk of injuring their children and generally have strained relationship with their infant and if not intervened into can have a long term effect on their growth and development.

A variety of tools like the Centre for epidemiologic studies of depression instrument, patient health questionnaire 9, postpartum depression scale, beck depression inventory and Edinburgh postpartum depression scale have been used to assess postpartum depression.(46) However the most common among them is the Edinburgh postpartum depression scale which is an easy to use, self-administered instrument containing 10 items ranked from 0 to 3 which reflects the experience over the past week and has been extensively validated.

In our study with the help of this tool, we aim to screen for depression postpartum and its strong predictors. Being a community based study, women who hesitate to

seek care or who are unaware of their condition will be identified and hence be a better representation of the burden of postpartum depression.

5 Methodology

5.1 Study Setting

The study was conducted in Kaniyambadi block of Vellore district, Tamil Nadu. The Kaniyambadi block has 82 villages and a population of 1,15,384. The community health department of Christian medical college, Vellore has established an integral health and development programme in Kaniyambadi block (CHAD). The health care is delivered through a 3 tier system. The first tier consists of a part time community health worker (PTCHW). She is a woman from the village selected by the community and covers a population of 1500. Many of the PTCHW's are trained birth attendants and have received a month's training in basic concepts of maternal and child health, immunization, nutrition, environmental sanitation and the importance of surveillance and their role in the same. PTCHWs are supervised by the health aide who is also a resident of the village and serves a population of 5000. One health aide supervises 3-4 PTCHWs. She has a minimum education up to high school and is trained for a year before recruitment. She visits each village at least once a week. The next tier consists of a public health nurse(PHN) who is a graduate nurse and covers a population of 20,000. She supervises 3-4 health aides and visits each village once fortnightly along with the health aide. The doctors are responsible for a population of 30,000. A doctor along with the nurse and health aide visits every village once a month to conduct the mobile clinic. The services provided at the clinic include curative services, antenatal care, management of chronic diseases such as hypertension, diabetes mellitus, bronchial asthma, dyslipidemia, psychiatric disease etc. If any person requires a referral to a health facility they are referred to the base hospital which is the third tier.

The base hospital is a 135 bedded hospital with out- patient department, labour room, surgical theatre and laboratory facilities.

The health information system of CHAD programme registers all health related events like all marriages, pregnancies, births, deaths and outbreaks of disease. These events are informed orally by the PTCHW to the health aide. The health aide visits each village at least once a week and during the visits verifies the information obtained by the PTCHW. Additionally, the health aide does home visits to follow up pregnant women, postpartum mothers and their babies, confirms immunization details and also documents the information provided by the PTCHW. The information obtained is validated by the PHN. Registration of deaths are done by the health aide and the cause of death is assigned by the doctor after verifying the verbal autopsy. When in doubt, a home visit is done to clarify the course of events. All the documentation is computerized with weekly entry made in the pregnancies and outcomes of registered pregnancies. Health aide receives a printout of women monthly who are 24, 30, 36, 42 and 48 weeks of gestation to help her plan her visits accordingly. Every week, the information is submitted to the statistician who compiles and analyses the information. The information generated is reviewed by the entire department on a monthly basis.

5.2 Study design

The study was a concurrent cohort study which studied the morbidity among women during puerperium. The association of each morbidity with various risk factors was also studied.

5.3 Duration of the study

The study was conducted over a period of 21 months from January 2016 to September 2017.

5.4 Materials and methods

The study proposal was approved by the Institutional Review board and ethics committee of Christian medical college, Vellore

Sample size calculation

$$\text{Sample size} = \frac{(1.96)^2 * P * Q}{d^2}$$

Taking the prevalence of postpartum anaemia (being the most common among postpartum morbidity) as 47% with d being 7% : (51)

$$n = \frac{(1.96)^2 * 47 * 53}{7}$$

$$= 203$$

5.5 Informed consent

Informed consent was obtained after explaining in detail in the local language about the study objectives, benefits to the participants and community and possible risks involved in participation. An information sheet was provided for future reference

along with contact details of the principal investigator. The consent was obtained in a written form in the form of a signature or a left thumb impression in cases where the participant was illiterate. Refer to Annexure 3 and 4.

5.6 Study procedure

Antenatal women in the third trimester of their pregnancy (>28 weeks of gestation) were chosen as the eligible population. These women were identified from the list maintained by the Health Information System of CHAD programme. A new list was sought monthly to account for the late registrations and the new entrants into the third trimester of pregnancy.

The inclusion criteria were:

- Only permanent residents of Kaniyambadi block

Who were planning to reside in the study area during both recruitment and follow up visits.

The exclusion criteria were:

- Among the permanent residents, Women who were planning to move out of study area after delivery and hence unavailable for follow up

The obtained list of women was given to the health aides in charge of the area and the subject's contact number was obtained. The women were then contacted over telephone and after confirming their eligibility they were approached by home visits to participate in the study. For women whose contact number was not available at

first, the health aides were requested to obtain the number during the subject's subsequent visit to the mobile clinic for antenatal check-up. During the first home visit by the principal investigator, the details of study were explained and their willingness to participate confirmed. The participants were requested to inform the principal investigator as soon as she delivered. They were provided with a home based record book. This book consisted of symptoms of the conditions looked for in the study written in the local language(Tamil). The conditions studied included puerperal sepsis, mastitis, urinary tract infection, surgical wound site infection, episiotomy site infection, anaemia and postpartum depression. The diagnostic criteria of these conditions are described in detail in Annexure 8. The participants were advised to inform the investigator if any of the listed symptoms were experienced during the follow up period. Additionally, they were advised to document details of management if any visit to a health facility was sought during the same.

The principal investigator maintained a diary with the expected delivery date of each participant in the study. Participants were called two weeks prior, one week prior and immediately after the expected delivery date to follow on the delivery date. The health aide in charge was approached in case any participant was not contactable over telephone. Meanwhile the base hospital birth register was reviewed twice weekly in case any participant delivered at same hospital. The first home visit by the principal investigator was made 7-10 days after delivery. During this visit, a semi structured questionnaire was administered in the local language. Refer Annexure 1. The questionnaire had information regarding socio-demographic details, previous obstetric history, past history of any medical illness, current obstetric and delivery

details and details on associated risk factors. Certain antenatal details were also noted from the antenatal record of the patient maintained by her at home. If the record was unavailable, the details were then obtained from the hospital record. Any symptoms experienced from the provided checklist were also asked for. Breast and abdominal examination was conducted ensuring privacy. However, for any perineal or pelvic complaints, subjects were referred to the base hospital for further management. Each health aide was provided with a list of study participants and their proposed home visit date (28 days after delivery) which was constantly being updated on a weekly basis as and when the subjects delivered. Simultaneously details regarding their own visits to the study subjects were updated as well. The final home visit was done by the principal investigator at 6-8 weeks after delivery. During this visit the participant was once again examined and asked for any symptoms experienced as it was done in the first visit after childbirth. In addition to that, the Edinburgh postpartum depression scale was explained to the subject. It is a self-administered questionnaire written in the local language(Tamil). If the participant was illiterate the questions were read out to them by the investigator and answered based on their replies. It consisted of 10 questions with each question having four answer options with scores ranging from 0 to 3. The total was out of 30 and a score greater than or equal to 9 was taken as testing screen positive.(52) Participants who screened positive were referred to the base hospital for further management. A 2 ml blood sample was taken to test for haemoglobin which was processed at the laboratory in the base hospital. A value of 12 and above was considered as normal, 11- 11.9 as mild anaemia, 8-10.9 as moderate anaemia and less than 8 as severe anaemia.(37)

The women who had already delivered when approached by the investigator, who were not contactable, who refused home visits after obtaining informed consent and whose expected delivery date was out of the time frame decided for recruitment were excluded from the study.

5.7 Data entry

Data entry was done using Epidata version 3.1. Data analysis was done using Statistical Package of Social Sciences (SPSS 20.0), licensed for use by the Department of Community Health, Christian medical college, Vellore.

5.8 Data analysis

5.8.1 Descriptive statistics

The sociodemographic characteristics and various other factors of the study population have been presented using frequency and percentages of categorical variables and mean for continuous variables The exposure factors are similarly described.

5.8.2 Risk factor analysis

Bivariate analysis was done to know the association between categorical variables using Chi square to determine statistical significance. Risk factors with p values less than 0.05were included in multivariate analysis.

5.8.3 Exposure variables

Baseline sociodemographic correlates, antenatal and birth details, details of comorbidity, antenatal haemoglobin, postpartum haemoglobin and score obtained on Edinburgh postpartum depression scale were categorized and analysed to ensure comparability.

- Age of the participants was classified as following groups for analysis,
    a. 18-20 years
    b. 21-23 years
    c. 24-26 years
    d. 27-29years
    e. 30-32 years
    f. 33-35 years
    g. >=36 years

  The median age of the participants which was 24 was used to categorize the participants for bivariate analysis.

- Age at marriage of the participants was classified as
    a. <18 years
    b. 18-21 years
    c. 22-25 years
    d. >=26 years

    The median age of 21 years was used to categorize the participants for bivariate analysis.

- Education of participant and husband was classified as

a. No schooling
b. Primary school
c. Middle school
d. High school
e. Intermediate/ Post high school diploma
f. Graduate/ Post graduate
g. Professional or Honours

For bivariate analysis it was categorized as High school and below and above high school

- Occupation of the participant and husband was classified as
  a. Homemaker (participant), Unemployed (Husband)
  b. Unskilled worker
  c. Semiskilled worker
  d. Skilled worker
  e. Semi professional
  f. Professional

  For the purpose of bivariate analysis participant's occupation was categorized as homemaker and others and participant's husband's occupation was categorized as semiskilled worker and below and skilled worker and above.
- Socioeconomic classification was done based on B G Prasad scale with income levels updated as of 2017.It was classified as
  a. Lower

b. Lower middle

c. Middle

d. Upper middle

e. Upper

For the purpose of bivariate analysis, it was categorized into lower and lower middle and others.

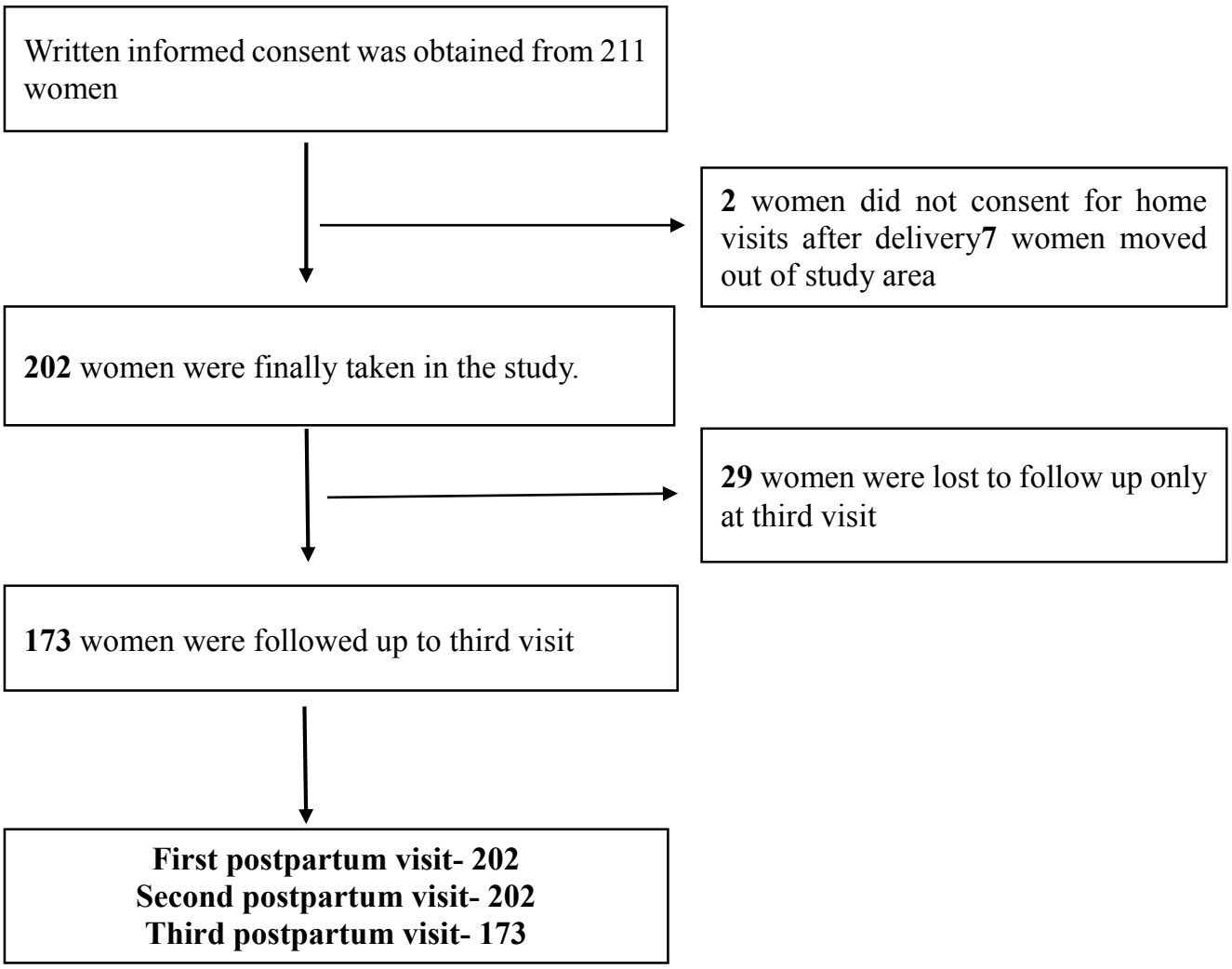
- Family type for bivariate analysis was categorized into
  a. Joint
  b. Nuclear and extended
- Parity for bivariate analysis was categorized into
  a. Primi
  b. Multi

5.8.4 Outcome variables:

- Antepartum and postpartum anaemia was classified based on the WHO cut off of Haemoglobin and categorized as
  a. <12 gm/dl- Anaemia present
  b. ≥12 gm/dl- Anaemia absent
- Postpartum depression was scored based on Edinburgh postpartum depression scale cut off score of 9 and was categorized as
  a. Score of <8- Depression absent
  b. Score of ≥9- Depression present
- Urinary tract infection was taken as infection present if the participant had a documentation of infection as tested by urine routine microscopy.

- Surgical wound site infection, Infection at the episiotomy site, mastitis and puerperal sepsis were self-reported.
- Infections for the purpose of bivariate analysis were categorized as presence and absence of infection

Figure 5.1 Flow Chart showing selection of participants



6 Results

A total of 211 women were approached to participate in the study. From which 2 women refused home visits after giving consent and 7 women moved out of the study area immediately after delivery. The remaining 202 women were followed at 7 days and 28 days postpartum At the third visit 29 women were not available and hence 173 women were followed up to 42 days.

6.1 Socio demographic characteristics

All the women (100%) recruited into the study were married. None were separated, divorced or a widow.

Table 6.1.1 Age distribution (n=202)

Age	Number	Percentage
18-20	20	9.9
21-23	63	31.2
24-26	59	29.2
27-29	34	16.8
30-32	16	7.9
33-35	4	2.0
≥36	6	3.0

All the participants were between 18 to 40 years. The median age was found to be 24 years.

Figure 6.1 Age of Participant (n=202)

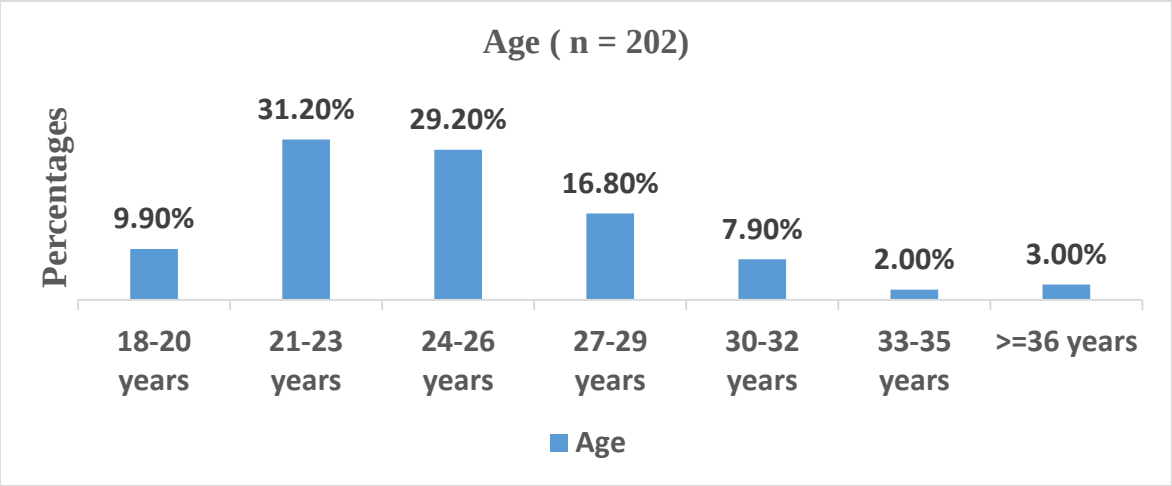


Table 6.1.2 Age at marriage (n=202)

Age at marriage	Number	Percentage
<18	11	5.4
18-21	110	54.5
22-25	54	26.7
>26	27	13.4

The age at marriage ranged from 15- 30 years with 11(5.4%) women being married at an age lesser than the legal age of eighteen. The remaining 7 (13.4%) women were married at 26 years and above. The median age at marriage was found to be 21 years.

Figure 6.2 Age at marriage (n=202)

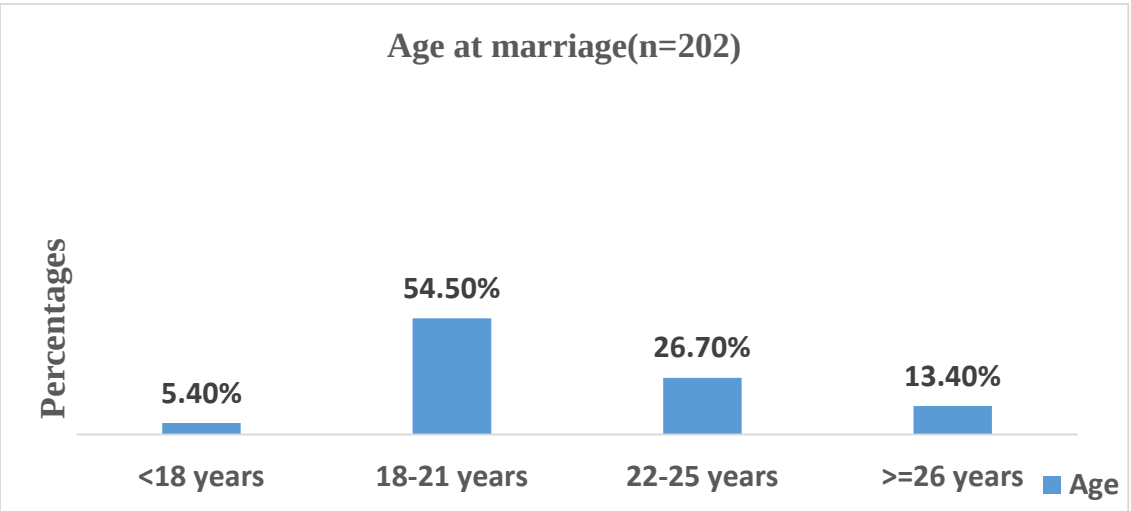


Table 6.1.3 Family type (n=202)

Family type	Number	Percentage
Nuclear	46	22.8
Joint	153	75.7
Extended	3	1.5

Among 202 women, 153 (75.7%) of the participants belonged to joint family. The median family size was found to be 6.

Table 6.1.4 Literacy status (n=202)

Literacy status	Number	Percentage
Illiterate	4	2.0
Read and write	198	98.0

Among 202 women, 198 (98%) of the women could both read and write. However,4 (2%) of them were illiterate.

Table 6.1.5 Educational status of the participant (n=202)

Education	Number	Percentage
No schooling	4	2.0
Primary school	7	3.5
Middle school	35	17.3
High school	83	41.1
Intermediate/Post high school diploma	27	13.4
Graduate/Postgraduate	44	21.8
Professional or Honors	2	1.0

The education qualification of the participant was based on the groupings as provided by the modified Kuppuswamy classification scale. Out of the total participants, 4 (2 %) of them did not receive any formal schooling. The highest education attained was high school by 83 women (41.1%), 35 (17.3%) had attained up to middle school and 7 (3.5%) up to primary school. There were women who were educated above high school with a post high school diploma being 27(13.4%), up to graduate/ postgraduate level being 44(21.8%) and professional/honours of 2 (1%).

Table 6.1.6 Educational status of the participant's husband (n=202)

Education	Number	Percentage
No schooling	3	1.5
Primary school	17	8.4
Middle school	43	21.3
High school	81	40.1
Intermediate/Post high school diploma	21	10.4
Graduate/Postgraduate	36	17.8
Professional or Honors	1	0.5

The education qualification of the participant's husband was based on the groupings as provided by the modified Kuppuswamy classification scale. This showed a similar distribution pattern as that of the participants with 3 (1.5 %) of them not receiving any formal schooling,17 (8.4%) attained up to primary school,43 (21.3%) had attained up to middle school and remaining 81 (40.1%) had attained high school. Women whose husbands were educated above high school with a post high school diploma were a total of 21 (10.4%), up to graduate or postgraduate level were 36 (17.8%) and professional honours was 1 (0.5%).

Figure 6.3 Educational status (n=202)

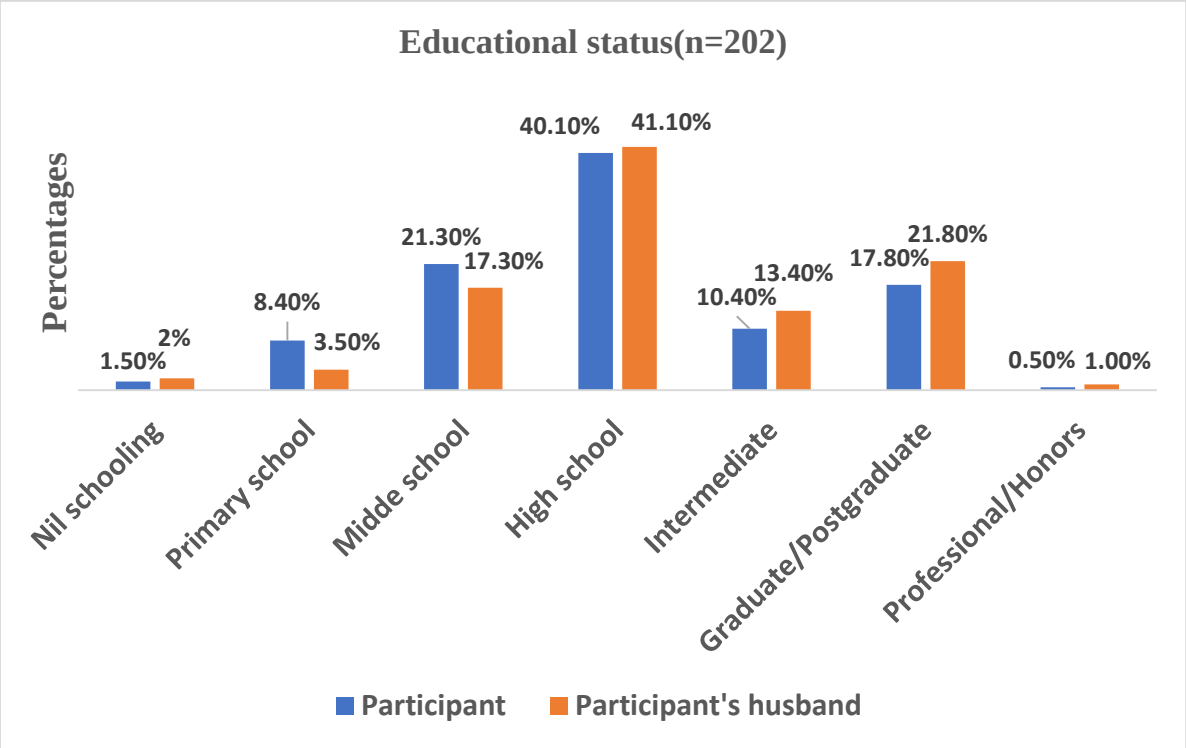


Table 6.1.7 Occupation of the participants (n=202)

Occupation	Number	Percentage
Homemaker	185	91.6
Unskilled worker	3	1.5
Semiskilled worker	1	0.5
Skilled worker	2	1.0
Semi professional	5	2.5
Professional	6	3.0

Occupation of the participants was based on the classification provided by modified Kuppuswamy classification scale. Most women were homemakers 185 (91.6%).

Table 6.1.8 Occupation of the participant's husband (n=202)

Occupation	Number	Percentage
Unemployed	1	0.5
Unskilled worker	39	19.3
Semiskilled worker	39	19.3
Skilled worker	51	25.2
Clerical/Shop owner/Farmer	30	14.9
Semi professional	21	10.4
Professional	21	10.4

Occupation of the participant's husband was based on the classification provided modified Kuppuswamy classification scale. Only 1(0.5%) of the men was unemployed. The highest proportion of 51 (25.2%) men were skilled workers, 78 (38.6%) men were unskilled and semiskilled workers and 30 (14.9%) men were either shop owners or farmers. Remaining 21 (10.4%) were professionally and semi-professionally employed.

Table 6.1.9 Socioeconomic class of participants (n=202)

SES class	Number	Percentage
Lower	29	14.4
Lower middle	90	44.6
Middle	42	20.8
Upper middle	30	14.9
Upper	11	5.4

Socioeconomic scores of the study participants were calculated based on B G Prasad 2017 classification, which takes into account per capita income. The per capita income among the participant's ranged from Rs. 500- 13,333 and the median was

found to be Rs. 1,666. Among the participants, 29 (14.4%) belonged to lower class , 90 (44.6%) belonged to lower middle class , 42 (20.8%) belonged to middle class, 30 (14.9%) belonged to upper middle and rest 11 (5.4%) belonged to upper class. The highest proportion was seen among those of lower middle class.

Figure 6.4 Socioeconomic class (n=202)

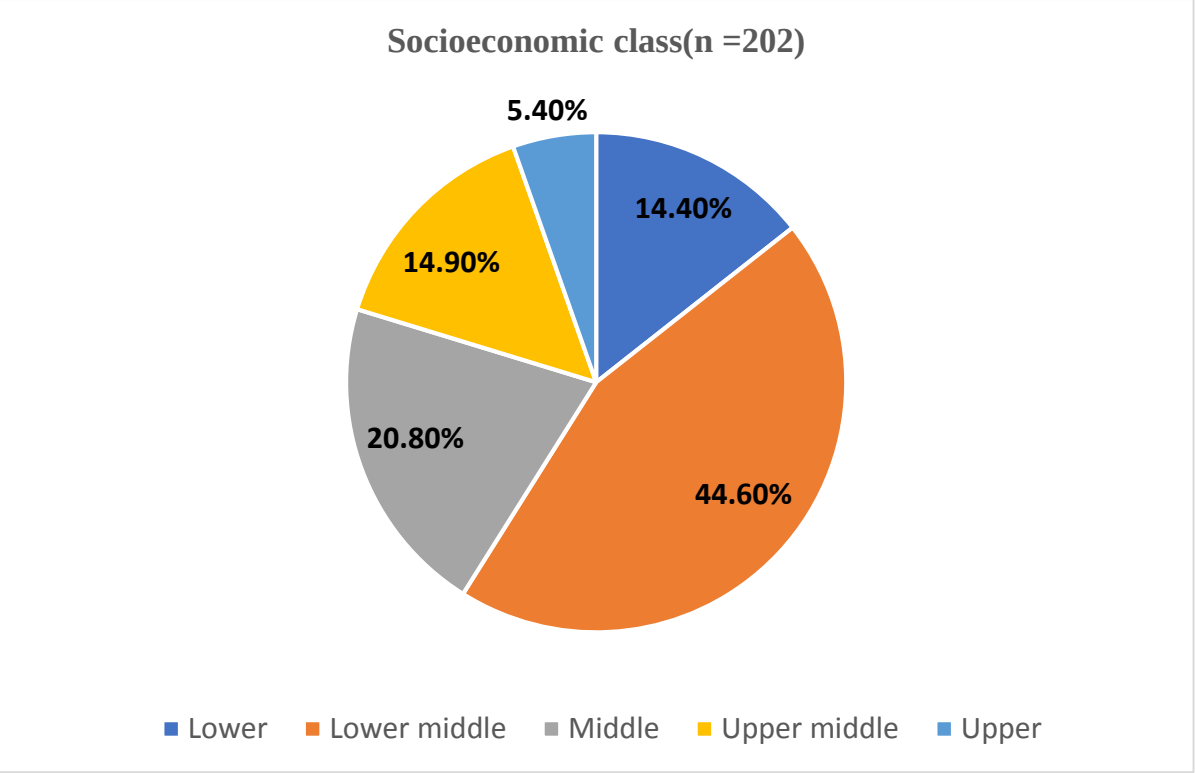


Table 6.1.10Summary table of Sociodemographic characteristics (n= 202)

Characteristic		Number	Percentage
Marital Status	Married	202	100
Age	< 24 Years	83	41.1
	>24 Years	119	58.9
Age at marriage	< 21 Years	96	47.5
	>21 Years	106	52.5
Type of family	Joint	153	75.7
	Nuclear and Extended	49	24.3
Literary Status	Illiterate	4	2.0
	Literate	98	98.0
Education of participant	High School and below	129	63.9
	Above High School	73	36.1
Education of participant's husband	High School and below	144	71.3
	Above High School	58	28.7
Occupation of participant	Homemaker	185	91.6
	Others	17	8.4
Occupation of participant's husband	Semi-skilled worker and below	79	39.1
	Skilled worker and above	123	60.9
Socioeconomic Status	Lower class	29	14.4
	Lower middle and others	173	85.6

6.2 Obstetric history and past history of illness

Table 6.2.1. Gravida (n =202)

Gravida	Number	Percentage
1	55	27.2
2-3	132	65.3
>3	15	7.4

Table 6.2.2 Parity (n=202)

Parity	Number	Percentage
0	72	35.6
1	99	49.0
2-3	30	14.9
>3	1	0.5

Table 6.2.3 Number of living children (n=202)

Living children	Number	Percentage
0	72	35.6
1	103	51.0
2-3	27	13.4

There were 55 (27.2%.) women who had conceived for the first time. Total of 72 (35.6%.) were primiparous and remaining 130 (64.4%) were multiparous.

Among the multiparous women, 103 (51.0%) had only one living child and 27 (13.4%) had more than one living child.

Table 6.2.4 Distribution of previous poor outcomes (n=147)*

Outcome	Number	Percentage
No previous poor outcome*	82	55.7
Abortion	57	32.8
Still birth	4	2.7
Early neonatal death	4	2.7
Under 5 death	4	2.7

*Gravida 1= 55 women had conceived for the first time, hence were excluded from the analysis

Out of the 147 women, 82 (55.7%) had no previous poor outcome, 57 (32.8%) women had abortions in the past, 4 (2.7%) had a previous still birth, 4 (2.7%) had a previous early neonatal death and remaining 4 (1.9%) had under 5 child death.

Table 6.2.5 History of chronic illness (n =202)

	Number	Percentage
Present	11	5.4
Absent	191	94.6

Table 6.2.6 Type of chronic illness (n =202)

Chronic illness	Number	Percentage
Hypothyroidism	8	4.0
Bronchial Asthma	2	1.0
Heart disease	1	0.5

Total of 191 (94.6%) did not have any comorbidity. Among the rest ,11 (5.4%) had a coexisting comorbidity from which 8(4%) had hypothyroidism, 2 (1 %) had bronchial asthma and 1 (0.5%) had history of heart disease. None of the participants had more than one chronic illness.

Table 6.2.7 Family history of psychiatric illness (n=202)

Psychiatric illness	Number	Percentage
Present	7	3.5
Absent	195	96.5

Family history of psychiatric illness was enquired. Only 7 (3.5%) women had a family history of psychiatric illness.

6.3 Characteristics of current pregnancy and delivery

Table 6.3.1 Risk factors in current pregnancy (n = 202)

Risk factors	Number	Percentage
Absent	103	50.9
Only1 risk factor	80	39.6
>1 risk factor	19	9.4

Table 6.3.2 Type and frequency of risk factors (n = 202)

Risk factor	Number	Percentage
Anaemia(n=199)*	105	52.7
Gestational diabetes mellitus	23	11.4
Gestational hypertension	8	4.0
Polyhydramnios	8	2.0
Oligohydramnios	7	3.5
Hepatitis B positive	4	2.0
Intrauterine growth restriction	4	2.0
Hypothyroidism	3	1.5
Multiple gestation	3	1.5
Prolonged infertility	2	1.0

Among the participants, 80 (39.6%) women had one risk factor and 19 (9.4%) women had more than 1 risk factor. Among the various risk factors, the highest was anemia which was 52.7% and second highest was gestational diabetes mellitus of 11.4%

Table 6.3.3 Supplementation during pregnancy (n=202)

	Supplementation	**Number**	**Percentage**
Oral	No	2	1.0
	Poor compliance	7	3.5
	Good compliance	193	95.5
Parenteral		44	21.8

As per WHO guidelines, pregnant women should receive iron supplementation for a minimum of 100 days .Intake less than that was taken as poor compliance.(36) Out of the 202 women, 2 were not compliant with the oral supplementation due to its gastrointestinal side effects Among the women who were compliant, 193 (95.5%) had good compliance and 7 (3.5%) were poorly compliant. Among the participants 44 (21.8%) received parenteral supplementation as well. None of the women received any blood transfusion during antenatal period.

WHO also recommends a minimum of 4 antenatal visits in pregnancy.(53) In our study a median of 12 visits were found which was much higher than the recommended. The number of visits ranged from 2- 27 visits.

Table 6.3.4 History Suggestive of Urinary Tract Infection in antenatal period (n=202)

Urinary tract infection	Number	Percentage
Present	21	10.4
Absent	181	89.6

21 (10.4%) of women had infection and 181 (89.6%) did not have infection.

Table 6.3.5 Fears experienced during pregnancy and immediate postpartum period (n=202)

Fear experienced	Number	Percentage
Pressure to have a male child	4	2.0
Fear since it is an unplanned pregnancy	5	2.5
Worry about care and growth of the baby	14	6.9
Worry due to existing debts	8	4.0

Women were asked if they experienced any unusual fears or had any anxieties or worries during pregnancy and immediate postpartum period. Among them, 14 (6.9%) women had concerns about the care and growth of the baby, 8 (4%) had worry due to existing debts, 5 (2.5%) had anxieties since it was an unplanned pregnancy and 4 (2%) women said that they had pressure from family since they desired a son.

Table 6.3.6 Interventions during delivery (n=202)

Intervention		Number	Percentage
Per vaginal examination done	No	22	10.9
	1 - 2	118	58.4
	3 - 4	36	17.8
	> 5	26	12.9
Vaginal insertion of catheter for induction	Yes	22	10.9
	No	180	89.1
Artificial rupture of membranes	Yes	59	29.2
	No	141	69.8
	Unaware	2	1.0
Insertion of urinary tube	Yes	56	27.7
	No	146	72.3
Episiotomy**	Yes	140	69.3
	No	27	13.3
Underwent Family planning operation (n=130)*	Yes	66	50.7
	No	64	49.2

*72 participants were not eligible for permanent sterilization since they were primiparous
** 35 participants had LSCS and hence did not have episiotomy

The participants were asked for the various interventions they underwent during delivery. They were asked about the number of per vaginal examinations they had during delivery. Among them, 118 (58.4%) women said that they had been examined 1-2 times., 22 (10.9%) women had a Foley's catheter introduced into the vagina to induce labour and 59 (29.2%) had their bag of membranes artificially ruptured. Urinary tube in order to drain urine to facilitate delivery or during Foley's catherization prior to caesarean section was done in 56 (27.7%) women. Women who had a caesarean section did not receive an episiotomy and hence among the rest 167 women, 140 (69.3%) had received an episiotomy. Women eligible for permanent

sterilization were 130. Among them 50.7% had done the operation and 64 (49.2%) did not.

Table 6.3.7 Pregnancy Outcome {n=205 (3 sets of twins)}

Outcome	Number	Percentage
Alive	201	98.0
Stillbirth	2	0.9
Early neonatal death	1	0.5
Infant death	1	0.5

Out of the three women who had multiple gestation during the current pregnancy, one woman had an intrauterine death of 1 twin and hence two women gave birth to a pair of twins each. Out of the 205 births, 201 (98.0%) were live births, 2 (0.9 %) were still births, 1 (0.5%) was an early neonatal death and 1 (0.5%) an infant death.

Table 6.3.8 Mode of delivery (n =202)

Mode	Number	Percentage
Normal vaginal delivery	153	75.7
Instrumental delivery	14	6.9
Caesarean section	35	17.3

Out of the all participants, 153 (75.7%) had normal vaginal delivery , 14 (6.9%) had instrumental delivery and remaining 35 (17.3%) had delivered by caesarean section.

Table 6.3.9 Place of delivery (n=202)

Place	Number	Percentage
PHC	09	4.5
CHAD hospital	142	70.3
Government hospitals	15	7.4
Vellore government hospital and medical college	15	7.4
CMC	17	8.4
Other private	04	2.0

Out of the all participants, 142 (70.3%) women delivered in CHAD, 21 (10.4%) women had delivered in private institutions like CMC and other private hospitals. The rest of them delivered in government PHC, hospitals and in the medical college and hospital of Vellore.

Table 6.3.10 Newborn Characteristics (n=205)*

Characteristics		Number	Percentage
Sex	Male	112	54.6
	Female	93	45.3
Birth weight	Low birth weight (< 2.5 kgs)	29	14.1
	Normal birth weight (≥ 2.5 kgs)	176	85.8
Gestational age*	Preterm (<37 weeks)	7	3.4
	Term (≥37 weeks)	195	95.1

*Date of last menstrual period is unknown in 3 participants and hence gestational age not calculated

Among the 205 births, 112 (54.6%) were males and 93 (45.3%) were females. In terms of birth weight, 176 (85.8%) of them had a normal birth weight as compared to 29 (14.1%) of them who had a low birth weight. Gestational age at delivery was calculated only for 199 women since the date of last menstrual period was unknown

for 3 participants. Out of them, 195 (95.1%) were term babies as compared to 7(3.4%) preterm babies.

Table 6.3.11 Family and Spouse Support (n=202)

Support		Number	Percentage
Family Support	Yes	187	92.6
	No	15	7.4
Spousal support	Yes	191	94.6
	No	11	5.4

All the women were enquired regarding their perceived support from their family and spouse. Among the participants ,15 (7.4%) women felt that they did not have sufficient family support and 11 (5.4%) women felt that they had poor support from their spouses.

Table 6.3.12 Haemoglobin levels during antenatal period (n=199)*

Haemoglobin(g/dl)	Number	Percentage
<8	1	0.5
8-10.9	49	24.3
11-11.9	55	27.2
>12	94	46.5

*Documented antenatal haemoglobin value was not available for 3 participants

Haemoglobin value during antenatal period was not available for 3 participants. Among the rest 199 women, 94 (46.5%) had normal haemoglobin values. The proportion of women with mild anaemia was 55 (27.2%), women with moderate anaemia was 49 (24.3%). Only 1 participant (0.5%) had severe anaemia.

6.4 Outcome variables

Table 6.4.1 Infections by the respective follow up period:

Infection	By 7days (n=202)	By 28days (n=202)	By 42 days(n=173)*
Puerperal sepsis	0	0	0
Mastitis	1	2	3
Urinary tract infection	1	2	3
Surgical wound site infection	9	10	11
Total	11	14	17

*29 women were lost to follow up at 42 days visit

The women were followed up thrice during puerperium. All the 202 women were followed up within 7-10 days after delivery (visit1) during which none developed puerperal sepsis, 1 developed mastitis, 1 developed urinary tract infection and 9 developed wound infections

Total of 202 women were followed up by 28 days after delivery (visit2)

- None had puerperal sepsis and the total number remained the same which is 0.
- One woman had mastitis and total number increased to 2.
- One woman had urinary tract infection and total number increased to 2.
- One woman had surgical wound site infection and total number increased to 10.

Total 29 women were lost to follow up after 28 days of delivery, thus only 173 women were followed up by 42 days after delivery (visit3).

- None had puerperal sepsis and the total number remained the same which is 0.

- One woman had mastitis and total number increased to 3.
- One woman had urinary tract infection and total number increased to 3.
- One woman had surgical wound site infection and total number increased to 11.

Table 6.4.2 Cumulative probability of infection.

Follow up period	Number of subjects	Number developing infections	Number lost to follow up	Population at risk	Probability of infection	1-probability of infection	Cumulative probability of no infection
1st (7days)	202	11	0	202	0.054	0.946	0.946
2nd (28days)	191	3	0	191	0.016	0.984	0.931
3rd (42days)	188	3	29	173.5	0.017	0.983	0.915

The cumulative probability of developing infection during the follow up period accounting for the women withdrawn from the study was calculated to be 8.6%.

Table 6.4.3 Postpartum Haemoglobin among the participants (n=173)*

Haemoglobin(g/dl)	Number	Percentage
<8	1	0.6
8-10.9	12	5.9
11-11.9	49	24.3
≥12	111	55.0

*29 women were lost to follow up at the third visit

Table 6.4.4 Postnatal Anaemia among the participants (n=172)*

Antenatal anaemia(g/dl)	Postnatal anaemia(g/dl)				Total
	<8	8-10.9	11-11.9	≥12	1
<8	0	0	0	1	1
8-10.9	1	5	17	20	43
11-11.9	0	2	17	34	53
≥12	0	5	14	56	98

*n=172 (Documented haemoglobin value of 1 participant not available)

On Comparison of anaemia Antepartum and postpartum, the following was noted.

- Only 1 woman was severely anaemic during antepartum. However post-delivery she had a normal haemoglobin value.
- Total of 43 women were moderately anaemic during antepartum period. Post-delivery out of the 43, around half of the them had normal haemoglobin values. However, 5 remained moderately anaemic and 1 became severely anaemic.
- Total of 53 women had mild anaemia during antepartum period. Post-delivery, 34 of them had normal haemoglobin values. However, 17 remained mildly anaemic and 2 became moderately anaemic.
- Total of 98 women had normal haemoglobin values during antepartum period. Post-delivery, 56 remained to have normal haemoglobin values. However, 14 became mildly anaemic and 5 became moderately anaemic.

Table 6.4.5 Change in Haemoglobin value (n=172)*

Haemoglobin value	Number	Percentage
Decreased	56	32.6
Remained same	3	1.7
Increased	113	65.7

*n=172 (Documented haemoglobin value of 1 participant not available)

Overall 32.6% of the women experienced a decrease in haemoglobin levels after delivery. A small proportion of 1.7% of them had no change in values during antepartum and postpartum period. However, majority that was 65.7% of them had an increase in the post-partum period. The mean antepartum haemoglobin with standard deviation was found to be 11.9($\pm$1.4) and that of postpartum haemoglobin was 12.3($\pm$1.1)

Table 6.4.6 Prevalence of postpartum depression (n=173*)

Screened for postpartum depression	Number	Percentage
Yes (Score $\geq$9)	48	27.7
No(Score <9)	125	72.3

*29 women were lost to follow up at the third visit

Total of 173 women were screened for postpartum depression. Based on the scores obtained on the Edinburgh postpartum depression scale, 48 women were found to have a score of >9 and hence the prevalence of depression was found to be 27.7%.

Table 6.4.7 Summary of morbidity in puerperal period

Any infections at visit 1 (n=202)	5.4%
Any infections at visit 2 (n =202)	1.5%
Any morbidity at visit 3 (n=173)	57.2%
Incidence of Mastitis(n=202)	1.0%
Incidence of Urinary tract infection(n=202)	1.0%
Incidence of Surgical wound site infection(n=79)	4.9%
Incidence of infection at Episiotomy wound site (n =140)	3.6%
Prevalence of postpartum anaemia (n=173)	35.8%
Prevalence of Postpartum depression(n=173)	27.7%

6.5 Risk factor analysis

Table 6.5.1 Association between risk factors and development of Postpartum infection (n=202)

Risk factor		Any infection developed		Tests of significance	
		Yes	**No**	**OR(95% CI)**	**P – value**
Age at marriage	<21 years	7(7.3%)	89(92.7%)	1.112(0.375-3.295)	0.848
	≥21 years	7(6.6%)	99(93.4%)		
Age	≥24 years	12(10.1%)	107(89.9%)	**4.542(0.989-20.861)**	**0.047***
	<24 years	2(2.4%)	81(97.6%)		
Education of participant	High school and below	10(7.8%)	119(92.2%)	1.450(0.438-4.798)	0.774
	High school and above	4(5.5%)	69(94.5%)		
Education of husband	High school and below	9(6.2%)	135(93.8%)	0.707(0.226-2.206)	0.548
	High school and above	5(8.6%)	53(91.4%)		
Occupation of participant	Homemaker	12(6.5%)	173(93.5%)	0.520(0.106-2.544)	0.333
	Unskilled worker and above	2(11.8%)	15(88.2%)		
Occupation of husband	Semiskilled worker and below	5(6.3%)	74(93.7%)	0.856(0.276-2.654)	0.787
	Skilled worker and above	9(7.3%)	114(92.7%)		

Family type	Joint	11(7.2%)	142(92.8%)	1.188(0.318-4.443)	1.000
	Nuclear and extended	3(6.1%)	46(93.9%)		
Socioeconomic status	Lower	3(10.3%)	26(89.7%)	1.699(0.444-6.503)	0.430
	Lower middle and above	11(6.4%)	162(93.6%)		
Parity	Primi	3(4.2%)	69(95.8%)	0.470(0.127-1.744)	0.387
	Multi	11(8.5%)	119(91.5%)		
Known chronic illness	Yes	2(18.2%)	9(81.8%)	3.315(0.643-17.086)	0.171
	No	12(6.3%)	179(93.7%)		
Risk factors in pregnancy	Yes	10(10.1%)	89(89.9%)	2.781(0.842-9.181)	0.100
	No	4(3.9%)	99(96.1%)		
Place of delivery	Government hospital	1(2.6%)	38(97.4%)	0.304(0.039-2.394)	0.313
	Private hospital	13(8.0%)	150(92.0%)		
Place of delivery	Primary and secondary hospital	11(6.6%)	155(93.4%)	0.781(0.206-2.954)	0.719
	Tertiary hospital	3(8.3%)	33(91.7%)		

*Statistically significant ($p<0.05$)

The various socio-demographic and obstetric risk factors were analyzed to find out whether they had any association with developing any infection during postpartum period. A woman' s age greater than or equal to 24 years (p value 0.047, OR 4.542, CI 0.989- 20.861) was found to be have a higher risk of developing infection. This was not however not statistically significant.

Table 6.5.2 Association between risk factors and development of postpartum depression (n = 173)

Risk factor		Postpartum depression		Tests of significance	
		Yes	**No**	**OR(95% CI)**	**P – value**
Age at marriage	<21 years	30(36.1%)	53(63.9%)	**2.264 (1.143-4.485)**	**0.018***
	≥21 years	18(20.0%)	72(80.0%)		
Age	≥24 years	25(24.8%)	76(75.2%)	0.701 (0.358-1.370)	0.298
	<24 years	23(31.9%)	49(68.1%)		
Education of participant	High school and below	33(29.5%)	79(70.5%)	1.281 (0.630-2.607)	0.494
	High school and above	15(24.6%)	46(75.4%)		
Education of husband	High school and below	36(28.8%)	89(71.2%)	1.213 (0.568-2.593)	0.617
	High school and above	12(25.0%)	36(75.0%)		
Occupation of participant	Homemaker	42(26.8%)	115(73.2%)	0.609 (0.208-1.778)	0.360
	Unskilled worker and above	6(37.5%)	10(62.5%)		
Occupation of husband	Semiskilled worker and below	19(29.2%)	46(70.8%)	1.125 (0.568-2.228)	0.735
	Skilled worker and above	29(26.9%)	79(73.1%)		
Family type	Joint	37(28.0%)	95(72.0%)	1.062 (0.483-2.337)	0.881
	Nuclear and extended	11(26.8%)	30(73.2%)		

Socioeconomic status	Lower	7(26.9%)	19(73.1%)	0.953 (0.373-2.435)	0.919
	Lower middle and above	41(27.9%)	106(72.1%)		
Parity	Primi	18(29.0%)	44(71.0%)	1.105 (0.554-2.202)	0.778
	Multi	30(27.0%)	81(73.0%)		
Known chronic illness	Yes	3(33.3%)	6(66.7%)	1.322 (0.317-5.513)	0.709
	No	45(27.4%)	119(72.6%)		
Risk factors in pregnancy	Yes	26(30.6%)	59(69.4%)	1.322 (0.678-2.577)	0.412
	No	22(25.0%)	66(75.0%)		
Place of delivery	Government hospital	9(29.0%)	22(71.0%)	1.080 (0.458-2.550)	0.860
	Private hospital	39(27.5%)	103(72.5%)		
Place of delivery	Primary and secondary hospital	35(24.8%)	106(75.2%)	0483 (0.216-1.076)	0.071
	Tertiary hospital	13(40.6%)	19(59.4%)		
Spousal support	No	7(63.6%)	4(36.4%)	**5.165 (1.438-8.548)**	**0.011***
	Yes	41(25.3%)	121(74.7%)		
Family support	No	9(64.3%)	5(35.7%)	**5.538 (1.751-7.515)**	**0.001***
	Yes	39(24.5%)	120(75.5%)		
Family history of psychiatric illness	Yes	2(33.3%)	4(66.7%)	1.315 (0.233-7.426)	0.670
	No	46(27.5%)	121(72.5%)		

Experienced pressure to have a male child	Yes	1(25.0%)	3(75.0%)	0.865 (0.088-8.528)	1.000
	No	47(27.8%)	122(72.2%)		
Experienced fear due to unplanned pregnancy	Yes	3(60.0%)	2(40.0%)	4.100 (0.663-25.342)	0.131
	No	45(26.8%)	123(73.2%)		
Experienced worry about care and growth of baby	Yes	5(55.6%)	4(44.4%)	3.517 (0.903-13.705)	0.118
	No	43(26.2%)	121(73.8%)		
Experienced worry about debts	Yes	2(28.6%)	5(71.4%)	1.043 (0.196-5.569)	1.000
	No	46(27.7%)	120(72.3%)		

*Statistically significant (p<0.05)

The data was analyzed to see if sociodemographic and obstetric risk factors along with perceived support from family and spouse as well as fears experienced during delivery and immediate postpartum period had any association with developing postpartum depression. Age at marriage less than <21 years (p value 0.018, OR 2.264, CI 1.143- 4.485), poor spousal support (p value 0.011, OR 5.165, CI 1.438-8.548) and poor family support (p 0.001, OR 5.538, CI 1.751- 7.515) were found to have significantly higher odds of developing postpartum depression as against the others.

Table 6.5.3 Multivariate analysis of risk factors on developing postpartum depression using binary logistic regression method

S.No	Variable	Yes	No	Crude OR (95%CI)	AOR (95%CI)	P value
1.	Marriage age <21 years	30 (36.1%)	53 (63.9%)	2.264(1.143-4.485)	**2.347 (1.163-4.737)**	**0.017***
2.	Poor spousal support	7 (63.6%)	4 (36.4%)	5.165(1.438-18.548)	**5.957 (1.597-22.223)**	**0.008***

*Statistically significant (p<0.05)

Table 6.5.4 Multivariate analysis of risk factors on developing postpartum depression using binary logistic regression method

S.No	Variable	Yes	No	Crude OR (95%CI)	AOR (95%CI)	P value
1.	Marriage age <21 years	30 (36.1%)	53 (63.9%)	2.264(1.143-4.485)	**1.986 (0.993-3.972)**	**0.052***
2.	Poor family support	9 (64.3%)	5 (35.7%)	5.538(1.751-17.515)	**4.950(1.543-15.883)**	**0.007***

*Statistically significant (p<0.05)

The effect of the various significant factors on postpartum depression were looked for after adjusting for possible confounders. In the first model, it was found that women who got married at less than 21 years had a 2.3 times higher odds of developing postpartum depression (p value 0.017). Women with poor spousal support had 5.9 times higher odds of developing postpartum depression (p value 0.008).

In the second model, it was found that women who got married at less than 21 years had a 1.9 times higher odds of developing postpartum depression (p value 0.052), women with poor family support had 4.9 times higher odds of developing postpartum depression (p value 0.007). Both family and spousal support were not included in the same model, as they seemed to cancel each other out.

Table 6.5.5 Association of risk factors and the development of postpartum anaemia (n=202)

Risk factor		Postpartum Anaemia		Tests of significance	
		Yes	No	OR(95% CI)	P - value
Age at marriage	<21 years	28(33.7%)	55(66.3%)	0.879 (0.47-1.643)	0.687
	≥21 years	33(36.7%)	57(63.3%)		
Age	≥24 years	35(34.7%)	66(65.3%)	0.938 (0.499-1.765)	0.843
	<24 years	26(36.1%)	46(63.9%)		
Education of participant	High school and below	42(37.5%)	70(62.5%)	1.326 (0.683-2.575)	0.403
	High school and above	19(31.1%)	42(68.9%)		
Education of husband	High school and below	46(36.8%)	79(63.2%)	1.281 (0.630-2.607)	0.494
	High school and above	15(31.2%)	33(68.8%)		
Occupation of participant	Homemaker	55(35.0%)	102(65.0%)	0.899 (0.310-2.604)	0.844
	Unskilled worker and above	6(37.5%)	10(62.5%)		
Occupation of husband	Semiskilled worker and below	23(35.4%)	42(64.6%)	1.009 (0.530-1.920)	0.979
	Skilled worker and above	38(35.2%)	70(64.8%)		

Family type	Joint	44(33.3%)	88(66.7%)	0.706 (0.344-1.449)	0.341
	Nuclear and extended	17(41.5%)	24(58.5%)		
Socioeconomic status	Lower	9(34.6%)	17(65.4%)	0.967 (0.403-2.322)	0.940
	Lower middle and above	52(35.4%)	95(64.6%)		
Parity	Primi	17(27.4%)	45(72.6%)	0.575 (0.293-1.130)	0.107
	Multi	44(39.6%)	67(60.4%)		
Known chronic illness	Yes	3(33.3%)	6(66.7%)	0.914 (0.220-3.790)	1.000
	No	58(35.4%)	106(64.6%)		
Risk factors in pregnancy	Yes	9(25.0%)	27(75.0%)	1.111 (0.385-3.208)	0.846
	No	9(23.1%)	30(76.9%)		
Place of delivery	Government hospital	11(35.5%)	20(64.5%)	1.012 (0.449-2.280)	0.977
	Private hospital	50(35.2%)	92(64.8%)		
Place of delivery	Primary and secondary hospital	53(37.6%)	88(62.4%)	1.807 (0.757-4.311)	0.178
	Tertiary hospital	8(25.0%)	24(75.0%)		
Antenatal anaemia	Yes	42(43.3%)	55(56.7%)	**2.418 (1.244-4.702)**	**0.008***
	No	18(24.0%)	57(76.0%)		
Compliance to supplementation	No	3(37.5%)	5(62.5%)	1.107 (0.255-4.798)	1.000
	Yes	58(35.2%)	107(64.8%)		

*Statistically significant ($p<0.05$)

Antepartum anaemia, sociodemographic factors and obstetric risk factors were examined for association with risk of developing postpartum anaemia. Presence of antepartum anaemia (p value 0.008, OR 2.418, CI 1.244- 4.702) was found to be associated with postpartum anaemia. This was statistically significant.

7 Discussion

Care during the Postpartum period is an integral component of maternal care worldwide. Studies done in India are often hospital based and consequently burden is often underestimated This study was conducted in the community and aimed to find out the morbidity profile among women after childbirth up to 6 weeks and their predisposing factors.

7.1 Sociodemographic related risk factors

In our study population the age of the women ranged from 18 to 40 years with the mean age found to be 24 years. 60.4% of them were between 21 and 26 years as given in Table 6.1.1 . Our study showed that women who were aged 24 years and above had a 4.5 times higher risk of developing an infection postpartum as compared to women less than 24 years of age. This association was however not significant.

The age at marriage of the women ranged from 15 to 30 years with the mean age as 21 years. Considering 18 as the legal age of marriage, 5.4% of the women were married below the legal age. 54.5% of women in the study population were married between 18 and 21 years. Mothers at a younger age may not be mentally prepared for childbirth and have undue anxieties regarding care of the child in the background of their existing concerns. This could be a factor leading them develop an unstable emotional state which puts them at risk for developing postpartum psychiatric illness. (54) Our study showed that women who got married at an age of less than 21 years had a 2.2 times higher risk of developing postpartum depression as compared to

women who got married at a later age. This was found to have a significant association after adjusting for possible confounders.

98% of the study participants were literate. Being literate correlates with better understanding of their health needs and health care service utilization. The socioeconomic classification was done based on the scores obtained on B G Prasad classification 2017 which included the per capita income of the participants. 85.6% of women belonged to lower middle class and above. A study done in Vietnam showed that women belonging to higher socioeconomic classes had better hygiene practices and hence lesser burden of infections which was consistent with our study. (55)However, these women are also expected to have better nutrition and hence lesser prevalence of conditions like anaemia. This is in contrary to our study findings which had a significantly large proportion of women identified with anaemia postpartum.

75% of our study participants belonged to a joint family. During the postpartum period of a woman, being surrounded by experienced members of the family have positive implications such as advise on better hygiene practices, adequate diet and sharing of past experiences of child care. On the contrary their presence can also pose a negative impact on the mother if they have a poor relationship affecting the mother's physical and emotional state in addition to having an effect on the care and growth of the baby.

Around 77.3% of women were educated up to high school and above. The same level of education was present among 68.8% of the participant's husbands. The proportion of no formal education among both was very low. Higher educational status will help

them be more sensitive to the various health issues the woman can face postpartum. A cross sectional study done on the postpartum practices of puerperal women and their influencing factors in three regions of China showed that the educational background of women and their spouses were found to have an influence on the women's postpartum practices. (56)

Majority of the women are homemakers with only 8.5% of them gainfully employed. The husbands were mainly skilled workers followed by semi-skilled and unskilled workers. A Homemaker is able to spend quality time with her newborn and provide timely breast feeds for the infant hence reducing her chances of developing any breast related infections.

7.2 Risk factors related to outcomes

The study population consisted of 64.4% of multiparous women and 35.6% of primiparous women. This is probably because of the traditional custom of primiparous women to have the delivery of their baby at their mother's house. This could have reduced the availability of primis for the study.

49% of the subjects had at least one risk factor in their pregnancy. From the various risk factors, anaemia was the commonest. A study done in south India showed that women who had antepartum anaemia were at a higher risk of developing postpartum anaemia.(57) In our study, those with antepartum anaemia had a 2.4 times higher risk of developing postpartum anaemia.

Among the women, 10.4% of them had developed urinary tract infection during antenatal period. A larger sample size considering that the prevalence of postpartum urinary infection is low would have probably showed association in our study population. We also studied if there was any association of having urine drained by a tube during delivery and risk of developing urinary tract infection postpartum. 27.7% of the women had a urinary tube inserted during delivery however there was no significant association found between the two.

Our study aimed to look for possible risk factors for postpartum depression. Women who had a subjective feeling that they had poor support from the family after childbirth had 5.5 times higher risk and women who felt that they had poor support from their spouse had 5.1 times higher risk of developing depression postpartum. This association was significant even after adjusting for confounding variables. Postpartum depression arises out of many social, psychological and emotional factors. The women were asked regarding the pressure they experienced from relatives who desired a son to be born, regarding undue worry about the care and growth of the baby, persistently feeling anxious if it was an unplanned pregnancy and worry about the repayment of existing debts they had and none of these were found to have any association as per our study.

None of the women had experienced puerperal sepsis during our study and hence the association of risk factors like having interventions such as artificial rupture of

membranes, more number of per vaginal examinations which were asked for could not be studied.

7.3 Overall magnitude of morbidity

Overall, incidence of developing any infection by 7 days postpartum was 5.4%, and by 28days postpartum was 1.5%. The incidence of mastitis was 1.0%, urinary tract infection was 1.0%, wound infection at episiotomy wound site was 3.6% and at surgical wound site infection was found to be 4.9%. The cumulative proportion of developing infection during period of puerperium was 8.6%. Apart from infections, anaemia and depression were also looked for in this study and around 57.2% of women had at least one of them by 42 days after childbirth. In our study, the prevalence of postpartum anaemia was found to be 35.8% and that of postpartum depression was found to be 27.7%.

A similar study done 20 years ago which followed 322 women up to 6 weeks after childbirth to identify the magnitude of puerperal morbidity in the block and its potential risk factors had found the incidence of urinary tract infection as 16%, abdominal wound infection as 14.6 %, episiotomy site infection as 6.6% and breast infections as 2.5% of the total infections. The prevalence of anaemia however in the study was 2.6%.

This shows that there has been a decline in the burden of postpartum infections in the last two decades. This could be attributed to the better access to health care services, increase in the number of institutional deliveries, improved literacy and educational

status, more awareness and acceptance of the health system by the women in pregnancy.

However, there has been an increase in the number of women with postpartum anaemia. This could be attributed to the increase in testing facilities for anaemia in women post-delivery, inadequate dietary patterns, increase in caesarean sections and instrumental deliveries which are prone to more blood loss during delivery.

Currently postpartum morbidity is being identified worldwide largely through passive surveillance. Passive surveillance relies on multiple factors like the cooperation of the health care providers from laboratories to doctors in reporting cases as and when they occur based on defined criteria. Although a simpler form of surveillance, it has the disadvantage of being incomplete in a large way. A more continuous approach is what is needed to be able to trace the incidence, distribution and trends of illness and be evaluated in a more consolidated and systematic fashion. This is what is referred to as active surveillance. This method however is very time consuming and requires much more resources. Considering the burden of illness during postpartum period such a surveillance technique is definitely recommended in order to reduce the load of illness on mothers postpartum.

The study findings will increase our knowledge on the actual burden of postpartum illness in the community and the factors predisposing to them. The study reveals that in postpartum period there is much more burden of anemia and depression as compared to infections. Unfortunately, most of this goes undiagnosed and unreported and our study being a community based one would be more reliable to identify such

missed events. It also showed that poor social support system from the family and spouse has a role to play in postpartum depression.

8 Conclusions

1. The incidence of developing any infection (urinary tract infection, puerperal sepsis, mastitis, wound infection) was found to be 5.4% by 7 days and 1.5% by 28 days postpartum and 8.6% by 42 days. A woman whose age is 24 years and above was found to have 4.5 times greater risk of developing infection postpartum (95% CI 0.989 – 20.861). However, this was not significant.
2. Among the infections, incidence of urinary tract infection was 1.0 %, mastitis was 1.0%, surgical site wound infection was 4.9%, episiotomy wound infection was 3.6%. None of the women in the study developed puerperal sepsis.
3. Prevalence of postpartum anaemia at 42 days was 35.8%. Women with antepartum anaemia had 2.4 times greater risk of postpartum anaemia (95% CI 1.168-4.418).
4. Prevalence of postpartum depression was 27.7%.
5. Those who were married before 21 years were found to have 2.3 times (95% CI 1.163 - 4.737) higher risk of postpartum depression
6. Women with poor family support had 4.9 times (95% CI 1.543 – 15.883) higher risk of developing postpartum depression.
7. Women with poor spousal support had 5.9 times (95% CI 1.597 – 22.223) higher risk of developing postpartum depression.

9 Limitations

1. 29 participants were lost to follow up by 42 days after delivery.
2. Temporary residents were excluded from the study since they were unavailable for follow up. This could underestimate the total burden of illness in the block.
3. Confirmation Bias- For participants who were administered the Edinburgh postpartum depression scale by the investigator since they were unable to comprehend it, there is a possibility of bias if the investigator had any prior notion of any stressful situation the participant was in.

10 **Recommendations**

1. Postpartum women should be actively monitored at regular time intervals. Currently there are preexisting guidelines on care of postpartum women. This includes maintenance of a register at the nearest health facility to follow such women regularly. However, this is not being implemented adequately. A more robust way of following up such women would help obtain more realistic figures of the magnitude of illness.
2. An improvement in the utilization of antenatal services has been seen in our study as well. Efforts should be made such that every antenatal woman who comes in contact with a health facility should receive a comprehensive counselling including the likely illness after childbirth and appropriate education should be done on the preventive measures including importance of breast feeding, safe hygiene practices and adequate diet.
3. Screening for postpartum depression should be included as part of the routine care for postpartum women. In areas where postpartum service utilization is less, women volunteers from the community can be trained to screen women and identify those at high risk for referral to a specialty center.

11 **Bibliography**

1. Maternal mortality rate - Country Comparison [Internet]. [cited 2017 Oct 23]. Available from: https://www.indexmundi.com/g/r.aspx?v=2223

2. WHO | Maternal mortality ratio (per 100 000 live births) [Internet]. WHO. [cited 2017 Oct 23]. Available from: http://www.who.int/healthinfo/statistics/indmaternalmortality/en/

3. Maternal Mortality Ratio (MMR) (per 100000 live births) | NITI Aayog, (National Institution for Transforming India), Government of India [Internet]. [cited 2017 Oct 23]. Available from: http://niti.gov.in/content/maternal-mortality-ratio-mmr-100000-live-births

4. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller A-B, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014;2(6):e323–e333.

5. Montgomery AL, Ram U, Kumar R, Jha P, Collaborators for TMDS. Maternal Mortality in India: Causes and Healthcare Service Use Based on a Nationally Representative Survey. PLOS ONE. 2014 Jan 15;9(1):e83331.

6. mmupdate-2002_eng.pdf [Internet]. [cited 2017 Oct 23]. Available from: http://www.unfpa.org/sites/default/files/pub-pdf/mmupdate-2002_eng.pdf

7. WHO | SDG 3: Ensure healthy lives and promote wellbeing for all at all ages [Internet]. WHO. [cited 2017 Oct 23]. Available from: http://www.who.int/sdg/targets/en/

8. 9789241506649_eng.pdf [Internet]. [cited 2017 Oct 23]. Available from: http://apps.who.int/iris/bitstream/10665/97603/1/9789241506649_eng.pdf

9. Souza JP, Cecatti JG, Haddad SM, Parpinelli MA, Costa ML, Katz L, et al. The WHO Maternal Near-Miss Approach and the Maternal Severity Index Model (MSI): Tools for Assessing the Management of Severe Maternal Morbidity. PLOS ONE. 2012 Aug 29;7(8):e44129.

10. National Research Council (U.S.), Committee on Population, Reed H, Koblinsky MA, Mosley WH, Workshop on the Consequences of Pregnancy MM and Mortality for Women, Their Families, and Society. The consequences of maternal morbidity and maternal mortality: report of a workshop [Internet]. Washington, DC: National Academy Press; 2000 [cited 2017 Oct 24]. Available from: http://public.eblib.com/choice/publicfullrecord.aspx?p=3375368

11. Nair M, Choudhury MK, Choudhury SS, Kakoty SD, Sarma UC, Webster P, et al. IndOSS-Assam: investigating the feasibility of introducing a simple maternal morbidity surveillance and research system in Assam, India. BMJ Glob Health. 2016 Apr 1;1(1):e000024.

12. Souza JP, Cecatti JG, Haddad SM, Parpinelli MA, Costa ML, Katz L, et al. The WHO Maternal Near-Miss Approach and the Maternal Severity Index Model (MSI): Tools for Assessing the Management of Severe Maternal Morbidity. PLOS ONE. 2012 Aug 29;7(8):e44129.

13. Vallely L, Ahmed Y, Murray SF. Postpartum maternal morbidity requiring hospital admission in Lusaka, Zambia – a descriptive study. BMC Pregnancy Childbirth. 2005 Feb 1;5:1.

14. Bang RA, Bang AT, Reddy MH, Deshmukh MD, Baitule SB, Filippi V. Maternal morbidity during labour and the puerperium in rural homes and the need for medical attention: A prospective observational study in Gadchiroli, India. BJOG Int J Obstet Gynaecol. 2004 Mar;111(3):231–8.

15. V2C3Filippi_011915.pdf [Internet]. [cited 2017 Oct 25]. Available from: http://dcp-3.org/sites/default/files/chapters/V2C3Filippi_011915.pdf?page=4

16. Say L, Chou D, Gemmill A, Tunçalp Ö, Moller A-B, Daniels J, et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014 Jun 1;2(6):e323–33.

17. b6.2.4.pdf [Internet]. [cited 2017 Oct 23]. Available from: http://www.kemh.health.wa.gov.au/development/manuals/O&G_guidelines/section b/6/b6.2.4.pdf

18. Montgomery AL, Ram U, Kumar R, Jha P, Collaborators for TMDS. Maternal Mortality in India: Causes and Healthcare Service Use Based on a Nationally Representative Survey. PLOS ONE. 2014 Jan 15;9(1):e83331.

19. WHO | The World Health Organization's infant feeding recommendation [Internet]. WHO. [cited 2017 Oct 23]. Available from: http://www.who.int/nutrition/topics/infantfeeding_recommendation/en/

20. Lactational mastitis [Internet]. [cited 2017 Oct 23]. Available from: https://www.uptodate.com/contents/lactational-mastitis

21. Egbe T obinchemti, Ngonsai D, Tchounzou R, Ngowe MN. Prevalence and Risk Factors of Lactation Mastitis in Three Hospitals in Cameroon: A Cross-Sectional Study. Br J Med Med Res. 2016 Jan 10;13:1–10.

22. India.pdf [Internet]. [cited 2017 Oct 27]. Available from: http://rchiips.org/NFHS/pdf/NFHS4/India.pdf

23. Scott JA, Robertson M, Fitzpatrick J, Knight C, Mulholland S. Occurrence of lactational mastitis and medical management: A prospective cohort study in Glasgow. Int Breastfeed J. 2008 Aug 25;3:21.

24. Farret TCF, Dallé J, da Silva Monteiro V, Riche CVW, Antonello VS. Risk factors for surgical site infection following cesarean section in a Brazilian Women's Hospital: a case–control study. Braz J Infect Dis. 2015 Mar 1;19(2):113–7.

25. Betrán AP, Ye J, Moller A-B, Zhang J, Gülmezoglu AM, Torloni MR. The Increasing Trend in Caesarean Section Rates: Global, Regional and National Estimates: 1990-2014. PLoS ONE [Internet]. 2016 Feb 5 [cited 2017 Oct 23];11(2). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4743929/

26. ijss_mar_oa19.pdf [Internet]. [cited 2017 Oct 23]. Available from: http://www.ijss-sn.com/uploads/2/0/1/5/20153321/ijss_mar_oa19.pdf

27. Zuarez-Easton S, Zafran N, Garmi G, Salim R. Postcesarean wound infection: prevalence, impact, prevention, and management challenges. Int J Womens Health. 2017 Feb 17;9:81–8.

28. Johnson A, Thakar R, Sultan A. Obstetric perineal wound infection: Is there underreporting? Br J Nurs Mark Allen Publ. 2012 Mar 6;21:S28, S30, S32-5.

29. Khaskheli M-N, Baloch S, Sheeba A. Risk factors and complications of puerperal sepsis at a tertiary healthcare centre. Pak J Med Sci. 2013;29(4):972–6.

30. Marwah S, Topden SR, Sharma M, Mohindra R, Mittal P. Severe Puerperal Sepsis-A Simmering Menace. J Clin Diagn Res JCDR. 2017 May;11(5):QC04-QC08.

31. ibyt09i11p627.pdf [Internet]. [cited 2017 Oct 23]. Available from: http://medind.nic.in/iby/t09/i11/ibyt09i11p627.pdf

32. Kassebaum NJ, Fleming TD, Flaxman A, Phillips DE, Steiner C, Barber RM, et al. The Global Burden of Anemia. Hematol Oncol Clin North Am. 2016 Apr 1;30(2):247–308.

33. India_volume_I_corrected_17oct08.pdf [Internet]. [cited 2017 Oct 23]. Available from: http://rchiips.org/nfhs/NFHS-3%20Data/VOL-1/India_volume_I_corrected_17oct08.pdf

34. Census of India, Govt. of India - Ministry of Home Affairs, Official web-site | We also count people in India [Internet]. [cited 2017 Oct 23]. Available from: http://www.censusindia.net/

35. Haider BA, Olofin I, Wang M, Spiegelman D, Ezzati M, Fawzi WW. Anaemia, prenatal iron use, and risk of adverse pregnancy outcomes: systematic review and meta-analysis. BMJ. 2013 Jun 21;346:f3443.

36. haemoglobin.pdf [Internet]. [cited 2017 Oct 27]. Available from: http://www.who.int/vmnis/indicators/haemoglobin.pdf

37. MANYAM SM-S. Strategy Planning for Sanitation and Hygiene Improvement in Tribal Areas of Andhra Pradesh.

38. Li XF, Fortney JA, Kotelchuck M, Glover LH. The postpartum period: the key to maternal mortality. Int J Gynecol Obstet. 1996 Jul 1;54(1):1–10.

39. Iyengar K. Early Postpartum Maternal Morbidity among Rural Women of Rajasthan, India: A Community-based Study. J Health Popul Nutr. 2012 Jun;30(2):213–25.

40. Gibbs RS. Clinical risk factors for puerperal infection. Obstet Gynecol. 1980 May;55(5 Suppl):178S–184S.

41. Henly SJ, Anderson CM, Avery MD, Hills-Bonczyk SG, Potter S, Duckett LJ. Anemia and insufficient milk in first-time mothers. Birth Berkeley Calif. 1995 Jun;22(2):86–92.

42. Sserunjogi L, Scheutz F, Whyte SR. Postnatal anaemia: neglected problems and missed opportunities in Uganda. Health Policy Plan. 2003 Jun 1;18(2):225–31.

43. Rakesh P, Gopichandran V, Jamkhandi D, Manjunath K, George K, Prasad J. Determinants of postpartum anemia among women from a rural population in southern India. Int J Womens Health. 2014 Apr 11;6:395–400.

44. Harsha Kumar H, Gupta S, Ruhela S, Tanya S. A Retrospective Study on Magnitude and Factors Associated with Anemia in Postnatal Period from Coastal South India. Ann Med Health Sci Res. 2014;4(5):775–9.

45. O'hara MW, Swain AM. Rates and risk of postpartum depression—a meta-analysis. Int Rev Psychiatry. 1996 Jan 1;8(1):37–54.

46. Sit DK, Wisner KL. The Identification of Postpartum Depression. Clin Obstet Gynecol. 2009 Sep;52(3):456–68.

47. WHO | Postpartum depression in India: a systematic review and meta-analysis [Internet]. WHO. [cited 2017 Oct 23]. Available from: http://www.who.int/bulletin/volumes/95/10/17-192237/en/

48. Chandran M, Tharyan P, Muliyil J, Abraham S. Post-partum depression in a cohort of women from a rural area of Tamil Nadu, India: Incidence and risk factors. Br J Psychiatry. 2002 Dec 1;181(6):499–504.

49. Shidhaye P, Giri P. Maternal Depression: A Hidden Burden in Developing Countries. Ann Med Health Sci Res. 2014;4(4):463–5.

50. Stewart DE, Robertson E, Dennis C-L, Grace SL, Wallington T. Postpartum depression: Literature review of risk factors and interventions. Tor Univ Health Netw Women's Health Program Tor Public Health. 2003;

51. Rakesh P, Gopichandran V, Jamkhandi D, Manjunath K, George K, Prasad J. Determinants of postpartum anemia among women from a rural population in southern India. Int J Womens Health. 2014 Apr 11;6:395–400.

52. Benjamin D, Chandramohan A, Annie IK, Prasad J, Jacob KS. Validation of the Tamil version of Edinburgh post-partum depression scale. J Obstet Gynecol India. 2005;55:241–243.

53. WHO | New guidelines on antenatal care for a positive pregnancy experience [Internet]. WHO. [cited 2017 Oct 27]. Available from: http://www.who.int/reproductivehealth/news/antenatal-care/en/

54. Bornstein MH. Parenting and child mental health: a cross-cultural perspective. World Psychiatry. 2013 Oct;12(3):258–65.

55. Hillström T. Socio-economic determinants of postnatal care in Vietnam. 2013.

56. Liu N, Mao L, Sun X, Liu L, Chen B, Ding Q. Postpartum practices of puerperal women and their influencing factors in three regions of Hubei, China. BMC Public Health. 2006 Nov 7;6:274.

57. Rakesh P, Gopichandran V, Jamkhandi D, Manjunath K, George K, Prasad J. Determinants of postpartum anemia among women from a rural population in southern India. Int J Womens Health. 2014 Apr 11;6:395–400.

Annexures

1. Study Proforma
2. B G Prasad Scale 2017
3. Informed Consent
4. Informed Consent- Tamil
5. Information Sheet
6. Information Sheet- Tamil
7. Edinburgh Postpartum depression scale – Tamil
8. Diagnostic criteria of symptoms- Tamil
9. Institutional Review Board (IRB) Approval

Annexure 1: Proforma for data collection

Study Id No: | | | | | | |

Hospital No: | | | | | | | |

SECTION A

1. Name: _____

2. Age: | | |

3. Village Name: _____

4. Marital status:

- Married (1)
- Divorced (2)
- Separated (3)
- Widow (4)

5. Age at marriage: | | |

6. Family Type:

- Nuclear (1)
- Joint (2)
- Extended (3)

7. Literacy status:

- Illiterate (1)
- Read only (2)
- Read and write (3)

8. Education:

a) Respondent's: | |
b) Respondent's husband: | |
c) Head of household (if not mentioned before): | |

9. Occupation:

a) Respondent's: | |
b) Respondent's husband: | |
c) Head of household (if not mentioned before): | |

Unemployed(1), Unskilled worker (2), Semi- skilled worker(3), Skilled worker(4), Clerical, shop owner , farmer(5), Semi- professional(6), Professional(7)

10. Total monthly income: | | | | | | | |

11. Number of family members: | | |

SECTION B

G | | P | | L | | A | | D | | SB | | END | |

	G1	G2	G3	G4	G5	G6	G7
Year of birth							
Place of delivery							
Mode of delivery							
Outcome							
Sex of child							
Complications							

Place of delivery	Mode of delivery	Outcome	Sex of child	Complications
1. Home delivery 2. PHC 3. CHAD 4. GH 5. GVMC 6. CMC	1. Normal vaginal delivery 2. Instrumental 3. Caesarean section	1. Alive 2. Dead 3. Still birth	1. Male 2. Female	High risk factors

12. Do you suffer from any of the below mentioned chronic illnesses:

Condition	Yes(1)	No(2)
Diabetes mellitus(a)		
Hypertension(b)		
Liver disease(c)		
Renal disease(d)		
Bronchial Asthma(e)		
Heart disease(f)		
Seizure disorder(g)		
Others-(h)		

13. Have you ever been diagnosed of psychiatric illness? Yes(1) ☐ No(2) ☐

a) If yes, please specify

_____

14. Has anyone in your family been diagnosed of psychiatric illness? Yes(1) ☐ No(2) ☐

a) If yes ,please specify

_____

15. Did you experience any complications during pregnancy? Yes(1) ☐ No(2) ☐

Condition	Yes(1)	No(2)
High sugars(Diabetes) (a)		
Restricted baby growth (b)		
More liquor (c)		
High blood pressure (d)		
Less liquor (e)		
More than 1 baby (f)		
Low haemoglobin (g)		
Others: (h)		

16. Mention the form of supplementation you had during pregnancy:

	Yes(1)	No(2)
Oral(a)		
Parenteral(b)		
Blood transfusion(c)		

17. Were you compliant with the supplementation provided to you? Yes(1) ☐ No(2) ☐

18. Were you diagnosed of urinary tract infection during pregnancy? Yes(1) ☐ No(2) ☐

19. Did you experience any fears such as:-

	Yes(1)	No(2)
Pressure to have a male child (a)		
Worry since it was an unplanned pregnancy (b)		
Worry about care and growth of the baby (c)		
Worry about your financial debt (d)		

SECTION C –

20. Approximately for how many hours did you experience leaking per vaginum? ☐☐

21. How many per vaginal examinations were done prior to your delivery?

	Yes(1)	No(2)
1-2 times		
2-4 times		
>4 times		

22. Foley's induction- Yes (1)☐ No(2)☐

23. Artificial rupture of membranes – Yes(1) ☐ No(2) ☐

24. Was a tube inserted to drain urine at any point during your delivery? Yes(1)☐ No(2) ☐

25. Did you have any stitches put after delivery? Yes(1) ☐ No(2) ☐

26. Did you undergo permanent sterilisation operation? Yes(1)☐ No(2) ☐

27. Date of delivery: ☐☐☐☐☐☐☐☐

28. Mode of delivery :

- Normal vaginal delivery (1)
- Instrumental delivery (2)
- Caesarean section (3)

29. Place of delivery :

- Home delivery (1)
- PHC (2)
- CHAD hospital (3)
- Government hospital (4)
- GVMC (5)
- CMC (6)

30. Outcome of pregnancy:

- Alive (1)
- Dead (2)
- Still birth (3)

31. Do you think you have:

a) Sufficient Family support Yes(1) ☐ No(2) ☐
b) Sufficient Spousal support Yes(1)☐ No(2) ☐

32. Did you experience any of the following complications after this delivery?

	Visit 1	Visit 2	Visit 3
a) <u>Any 2 of the following</u> □ Pain in lower abdomen □ Fever □ Increased quantity of vaginal discharge □ Foul odour of vaginal discharge □ Pain during vaginal discharge	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)
b) <u>Any 2 of the following</u> □ Fever with/without chills □ Breast pain □ Painful mass on the breast	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)
c) <u>Any 2 of the following</u> □ Burning pain during urination □ Frequent feeling to urinate □ Urge to urinate □ Fever with or without chills □ Pain in lower abdomen	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)
d) <u>At the site of the wound-</u> (All 3) □ Pain associated with redness and warmth □ Swelling □ Pus discharge	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)	□ Yes(1) □ No(2)

33. Last menstrual period:

34. Date of registration for antenatal care:

35. Haemoglobin at

    a. first visit with date:

    b. repeat haemoglobin with date (if applicable):

36. Weight at first visit
37. Weight prior to delivery
38. Number of antenatal visits

Annexure 2: BG Prasad scale 2017

Classification

Socioeconomic class	Per capita monthly income
Upper class	≥6254
Upper middle class	3127-6253
Middle class	1876-3126
Lower middle class	938-1875
Lower class	<938

Annexure 3: Written Informed Consent Document

Study Title: Incidence and risk factors for morbidity among puerperal women in Kaniyambadi block, Vellore- a prospective cohort study.

Patient ID No: _____

Subject's Name:

Date of Birth / Age:

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or
Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____
Signature or thumb impression of the Witness: _____
Date: _____/_____/_____

Name & Address of the Witness: _____

Annexure 4: Facsimile of Informed Consent Document - Tamil

ஒப்புதல் படிவம்

<u>ஆய்வின் பெயர் :</u>

கணியம்பாடி தொகுதியில் உள்ள (பிரசவ வயது) குழந்தை பெற்று கொள்ளும் தகுதியுடைய பெண்களின் நோயுற்ற நிலையும் அதன் நோய்தாக்கத்தையும் அறிந்து கொள்ள ஓர் பெரிய அளவிளான ஆய்வு.

பங்கேற்பவரின் பெயர் : _____

பிறந்த தேதி, வயது : _____

<u>ஆய்வு எண் :</u>

1. _____ தேதியில் இந்த ஆய்வை பற்றி எனக்கு கொடுக்கப்பட்ட தகவல் தாளை நான் படித்து உள்ளேன் மற்றும் புரிந்து கொண்டேன். எனக்கு இருந்த சந்தேகங்களும் கேட்டு தீர்க்கப்பட்டன. [ ]
2. நான் இந்த ஆய்வில் பங்கேற்பது என்னுடைய தனிப்பட்ட முடிவுதான் என்பதை புரிந்து கொண்டேன். இந்த ஆய்விலிருந்து எந்நேரத்திலும் எந்த காரணமும் இன்றி வெளியேற எனக்கு முழு உரிமை உண்டு என்று அறிவேன். இதனால் என்னுடைய மற்றும் எனது குடும்பத்தின் மருத்துவ வசதிகள் எந்த விதத்திலும் பாதிக்கப்படாது என்பதையும் நான் அறிவேன். [ ]
3. ஆய்வாளர்கள் எனது மருத்துவ பதிவேடுகளை எந்நேரத்திலும் இந்த ஆய்வுக்காகவும், இனி வரும் இது சம்பந்தப்பட்ட வேறு ஆய்விற்காகவும் எனது உத்தரவு இன்றி பயன்படுத்திக் கொள்ள சம்மதிக்கிறேன். ஆனால் இது எதிலும் எனது பெயரோ அல்லது என்னைப்பற்றிய தகவல்களோ வெளியில் யாருக்கும் தெரியவராது என்று அறிவேன். [ ]
4. இந்த ஆய்வின் முடிவுகளும் மற்ற தகவல்களும் மருத்துவ ரீதியாக அல்லது அறிவியல் நோக்கத்திற்கு பயன்படுத்த நான் எந்த தடையும் கூற மாட்டேன். [ ]
5. மேல் கொடுக்கப்பட்டுள்ள இந்த ஆய்வில் பங்கெடுக்க முழு சம்மதம் அளிக்கிறேன். [ ]

பங்கேற்பவர் அல்லது சட்டரீதியான பிரதிநிதியின் கையொப்பம் அல்லது விரல் ரேகையின் அச்சு.

பங்கேற்பவரின் பெயர் _____

பங்கேற்பவரின் கையொப்பம் _____

தேதி : _____

பிரதிநிதியின் பெயர் _____

பிரதிநிதியின் கையொப்பம் _____

தேதி : _____

ஆய்வாளரின் பெயர் _____

ஆய்வாளரின் கையொப்பம் _____

தேதி : _____

சாட்சியின் பெயர் மற்றும் முகவரி _____

சாட்சியின் கையொப்பம் _____

தேதி : _____

Annexure 5: Information Sheet

Information Sheet

Greetings! I am Dr. Anjali S. Nair. I am currently employed at CHAD hospital, Bagayam and am conducting a study, the details of which will be provided to you in this sheet and a copy will be given to you. Kindly go through it carefully and feel free to ask any questions regarding this. You may ask questions at any time even after the start of the study. Your participation in this study is purely voluntary and you are free to withdraw from this at any point. If you withdraw, this will not stop the medical care provided to you and your family by the hospital. Also, you will not receive any incentive for answering questions or for being part of this study.

Purpose of the study-

During the period of pregnancy every woman takes special care of her health because it will benefit the growth of her child. However, after delivery this aspect is completely neglected. This study will help us identify the common health problems faced by a woman in the initial period after delivery and take appropriate management steps to address those issues. This will help us to improve the mother's health as a whole.

Methods-

- Details of your residence, contact number and current pregnancy check-up will be obtained from the CHAD hospital records.

- After obtaining your verbal consent over telephone to participate in the study, you will be visited at your house thrice after delivery (first will be at 7-10 days after delivery and second visit will be at 6 weeks) at a time convenient for you. Second time you will be visited by the nurse.

- In the first visit, after your written consent, you will be provided with a diary. The diary will have the symptoms to be looked for daily and if you experience any of the same you would need to mark them in it. The diary will be checked by me during the subsequent house visit (at 6 weeks after delivery). Also I will be contacting you once in two weeks to enquire about any problems experienced by you which are part of the study.

- During my first visit, I will ask you details about your previous and current pregnancy.

- During the 6-week period, in case any further evaluation is required, a referral letter will be given and you can seek further advice in a hospital of your choice, the outcome of which will be followed up by me.

- Blood test for haemoglobin and sugars will be taken at the third house visit and the symptom diary will be collected then.

Approximate duration of this study-

1 year 1 month (February 2016- June 2017)

Expected cost during the study-

- There are no expenses for you during this study.
- Investigations will be done free of cost.

Description of the discomforts, inconveniences, risk factors that can be reasonably expected as a result of participation in this study-

- The questions that will be asked may not cause any discomfort to you as they are focussed only on assessing the details of your previous and current pregnancy, childbirth and health condition after delivery.
- Blood test for further evaluation will be taken if and when required during the house visit. There will be very minimal pain experienced while taking the sample.

Unforeseeable risk-

There are no such risks expected during this study.

Compensation in view of study related injury-

There is no study related injury expected from this study.

Anticipated benefits from this study-

This study aims to identify the common health problems faced during the first 6 weeks after delivery. Once diagnosed of any illness appropriate management will be provided at CHAD hospital for the same.

Circumstances under which the principal investigator may withdraw you from the study participation-

If you wish not to answer questions or do not want us to contact or meet you regarding this particular study, you will be withdrawn from the study. As mentioned earlier, if you withdraw, this will not affect the medical care provided to you and your family.

What happens if you choose to withdraw from the study participation-

The information you give us will not be used for any other purpose. All collected information will be destroyed.

Confidentiality-

Your identity will not be revealed to anyone else, however the summary details of the study may be used for publication for scientific purpose. If certain questions appear to be as personal, they will be asked to you in a confidential manner ensuring your privacy.

Contact information-

If you have any queries about this study, kindly contact me on
Dr .Anjali Nair

9952707961

Annexure 6: Information Sheet – Tamil

வேலூர், கணியம்பாடியிலுள்ள குழந்தை பெற்றிருக்கும் பெண்களின் உடல்நலக்குறைபாட்டின் நிகழ்வு மற்றும் காரணிகளைக் கண்டறியும் ஆய்வு

வணக்கம் நான் டாக்டர் அஞ்சலி நாயர். நான் பாகாயம் சாட் மருத்துவமனையில் வேலை செய்கிறேன்.இந்த தகவல் தாளில் நான் செய்யும் ஆய்வினை பற்றிய விளக்கங்கள் மற்றும் அதில் உங்கள் பங்கு பற்றியும் விளக்கி உள்ளேன் இதன் நகல் உங்களுக்குக் கொடுக்கப்படும். அதனை நீங்கள் நன்கு வாசித்து உங்கள் சந்தேகங்களையும் தீர்த்துக்கொள்ளலாம். எந்த நேரத்திலும் கேள்விகள் கேட்க உங்களுக்கு சுதந்திரம் உண்டு. இந்த ஆய்வில் உங்களது பங்கேற்பு முற்றிலும் உங்களது சொந்த விருப்பதினாலே இருக்கவேண்டும். இதிலிருந்து எந்த நேரத்திலும் விலகிக்கொள்ள உங்களுக்கு முழு உரிமை உண்டு.

நீங்கள் இந்த ஆய்விலிருந்து விலகுவதாலோ அல்லது பங்கேற்க மறுப்பதாலோ CHAD மருத்துவமனையில் உங்களுக்கு அளிக்கப்படும் சிகிச்சை நிறுத்தப்பட மாட்டாது. இந்த ஆய்வில் கலந்து கொள்வது உங்கள் சொந்த விருப்பத்தில் இருக்கவேண்டும்.

நீங்கள் இந்த ஆய்வில் கலந்துகொள்ள முடிவு செய்யும் பட்சத்தில் அதை உறுதி செய்யும் விதமாக ஒரு ஒப்புதல் படிவத்தில் கையெழுத்திட வேண்டும்.

ஆய்வின் நோக்கம் :

கர்ப்பமாய் இருக்கும் எந்த பெண்ணும் தனது உடலை நன்கு கவனித்து கொள்வது வழக்கம். ஏனென்றால் அது தனது குழந்தையின் வளர்ச்சிக்கு அத்தியாவசியம். ஆனால் இது பிரசவத்திற்கு பின்பு அப்படியே நிராகரிக்கப்படுகிள்ற ஒரு காரியம்.

இந்த ஆய்வு பிரசவத்திற்கு பிறகு, பெண்களுக்கு ஏற்படும் உடல் நலம் சம்பத்தப்பட்ட பிரச்சனைகள் என்ன என்பதை கண்டறிய உதவும். இந்த பிரச்சனைகளை தவிர்க்க எவற்றில் கவனம் செலுத்த வேண்டும் என்பதும் தெரியவரும். இந்த ஆய்வின் முடிவு அறிவியல் பதிப்புகளுக்காக பயன்படுத்தபடும், அவ்வாறு பயன்படுத்தப்படும் பட்சத்தில் தங்களை பற்றிய விவரங்களின் வெயிடப்பட மாட்டாது.

இந்த ஆய்வின் முழு கால அளவு:

இந்த ஆய்வு ஜனவரி – செப்டம்பர் 2017 வரை நடத்தப்பட உள்ளது. ஆய்வில் பங்கேற்போரின் விலாசம் தொலைபேசி / கைப்பேசி எண், மருத்துவ ஆவனங்கள்,

தற்போதைய பிரசவம் பற்றிய விவரங்கள் CHAD மருத்துவமனை பதிவுகளில் இருந்து பெறப்படும்.

ஆய்வு நடத்தப்படும் விதம்:

நீங்கள் கர்ப்பம் தரித்து இருக்கும் காலத்தில் நாங்கள் தங்கள் வீட்டிற்கு வந்து இந்த ஆய்வு பற்றி தெரிவிப்பதற்காகவும், ஒப்புதல் பெறுவதற்காகவும் வருவோம்.

பிரசவத்திற்கு பிறகு முதல் ஆறுவார காலத்தில் பெண்கள் எதிர்நோக்க கூடிய உடல்நல பிரச்சனை தொடர்பான தகவல் தாள் கொடுக்கப்படும்.

அந்தத்தாளில் கூறப்பட்டுள்ள பிரச்சனைகளை ஏதேனும் தாங்கள் அனுபவித்தால் எனக்கு தகவல் கொடுக்கவும். அதற்கு நாங்கள் தகுந்த நடவடிக்கை எடுப்போம்

தங்களுக்கு குழந்தை பிறந்த பின்பு தங்களை தங்கள் வீட்டிலேயே மூன்று முறை சந்திக்க திட்டமிட்டுள்ளோம். முதல் முறை 7–10 நாட்களிலும், 21–28 நாட்களிலும், 6 வாரத்திலும்

ஆதலாள் இயன்ற விரைவில் எனக்கு தகவள் அளிக்கவும்:

மேற்கூறிய சந்திப்புகளில் முதல் மற்றும் மூன்றாம் சந்திப்புகள் மருத்துவராலும் இரண்டாம் சந்திப்பு செவிலியராலும் நடத்தப்படும். முதல் முறை தங்களது தற்போதைய மற்றும் முந்தய பிரசவம் பற்றிய விளக்கங்கள் கேட்கப்படும்.

இந்த 6 வார காலத்தில் மேற்கூறிய பிரச்சனைகள் தங்களுக்கு ஏற்பட்டாலோ அதற்கு பரிசோதனைகள் தேவைப்பட்டாலோ தாங்கள் விரும்பும் மருத்துவமனையை அணுகலாம்.

6வது வாரத்தின் ஹீமோகுளோபின் அளவு தெரிந்து கொள்ள ஒரு இரத்த பரிசோதனை செய்யப்படும். மேலும் கர்ப்ப காலத்தில் தங்களுக்கு சர்க்கரை இருப்பதாக கண்டறியப்பட்டால் இந்த சந்திப்பின் போது இரத்ததில் உள்ள சர்க்கரை அளவு பரிசோதிக்கப்படும்.

ஆய்வின்போது தங்களுக்கு என்ன செலவு நேரிடலாம்:

மேற்கூறிய பரிசோதனைகளுக்கு எந்த கட்டணமும் கிடையாது. இந்த ஆறு வார காலத்தில் மேற்கூறிய பிரச்சனைகள் ஏதேனும் நேர்ந்தால் அதற்கு தேவைப்படும் பரிசோதனைகளையும், மருத்துவ செலவும் தங்களுக்கு எந்த செலவும் கிடையாது. இந்த பரிசோதனைகளுக்கும் எங்களால் முடிந்த உதவி அளிக்கப்படும்.

ஆய்வில் ஏதேனும் ஆபத்துகள் உண்டா ?

- இந்த ஆய்வால் தங்களுக்கு எந்த ஆபத்தும் கிடையாது.
- இரத்த பரிசோதனையின் போது மட்டும் ஊசியால் ஏற்படும் வலி உண்டாகும்.

என்ன காரணங்களை முன்னிட்டு நீங்கள் இந்த ஆய்விலிருந்து நீக்கப்பட முடியும்:

தங்களிடம் கேட்கப்படும் கேள்விகளுக்கு பதில் அளிக்க விருப்பம் இல்லை என்றாலோ, நாங்கள் தங்களை சந்திப்பதிலோ தொடர்புகொள்வதிலோ விருப்பம் இல்லை என்றாலோ, ஆய்வாளர் தங்களை ஆய்வில் இருந்து நீக்கலாம்.

அவ்வாறு நீக்கப்படும் பட்சத்தில் தங்களைப் பற்றிய ஆய்வு சம்மந்தமான தகவல் அனைத்தும் அழிக்கப்படும். மேலும் தங்களுக்கு அளிக்கப்படும் சிகிச்சை எதுவும் நிறுத்தப்படாது.

தொடர்பு தகவல்

உங்கள் சந்தேகங்களை தீர்த்துக்கொள்ள நீங்கள் அழைக்க வேண்டிய எண்

டாக்டர். அஞ்சலி நாயர் –

Annexure 7: Facsimile of Postpartum Depression Scale – Tamil

EDINBURGH POSTNATAL DEPRESSION SCALE
TAMIL VERSION

1. வேடிக்கையான நிகழச்சிகளை பார்த்து சிரிக்க முடியும்

   அ. எப்பொழுதும் என்னால் முடிந்த அளவு
   ஆ. எப்பொழுதாவது
   இ. கண்டிப்பாக எப்பொழுதாவது
   ஈ. முடியவே முடியாது

2. மகிழ்ச்சியான நிகழ்ச்சிகளுக்காக எதிர்நோக்கி கொண்டிருக்கிறேன்

   அ. முடிந்த அளவு செய்திருக்கிறேன்
   ஆ. முன்பைவிட சிறிது குறைந்துள்ளேன்
   இ. கண்டிப்பாக முன்பைவிட குறைந்துள்ளேன்
   ஈ. இல்லை

3. தவறான காரியங்கள் நிகழ்ந்த போது நான் என்னையே குறை கூறி உள்ளேன்

   அ. ஆம், எல்லா நேரத்திலும்
   ஆ. ஆம் சில நேரங்களில்
   இ. எப்பொழுதாவது
   ஈ. ஒருபோதும் இல்லை

4. தேவையற்ற காரணத்திற்காக நான் கவலைப்பட்டும், பயந்தும் உள்ளேன்.

   அ. இல்லவே இல்லை
   ஆ. எப்பொழுதாவது
   இ. ஆம் சில நேரங்களில்
   ஈ. ஆம், அடிக்கடி

5. ஒன்றுமில்லாத காரணத்திற்காக பயந்த உணர்வும் மற்றும் பதட்ட உணர்வும் அடைந்துள்ளேன்.

   அ. ஆம், நிறைய நேரம்
   ஆ. ஆம், சிலநேரம்
   இ. இல்லை எப்பொழுதாவது
   ஈ. இல்லவே இல்லை.

6. என் மீது சுமை ∴ பாரம் அதிகரித்து உள்ளது.

அ. ஆம், நிறைய நேரங்களில் என்னால் எதிர்த்து சமாளிக்க முடிவதில்லை

ஆ. ஆம், சில நேரங்களில் என்னால் முன்பு மாதிரி சமாளிக்க முடிவதில்லை

இ. இல்லை, நிறைய நேரங்களில் நன்றாக சமாளித்து உள்ளேன்

ஈ. இல்லை, எப்பொழுதும் சமாளித்து உள்ளேன்.

7. தூக்கமின்மையால் நான் மகிழ்ச்சியாக இல்லை.

அ. ஆம், எல்லா நேரமும்
ஆ. ஆம், அடிக்கடி
இ. எப்பொழுதாவது
ஈ. இல்லவே இல்லை

8. துக்கமான மற்றும் மகிழ்ச்சியற்ற நிலையை உணர்ந்துள்ளேன்.

அ. ஆம், எல்லா நேரமும்
ஆ. ஆம், அடிக்கடி
இ. எப்பொழுதாவது
ஈ. இல்லவே இல்லை

9. நான் அழுகையினால் சந்தோஷமின்றி இருக்கிறேன்∴

அ. ஆம், எல்லா நேரமும்
ஆ. ஆம், அடிக்கடி
இ. எப்பொழுதாவது
ஈ. இல்லவே இல்லை

10. நான் என்னையே கொள்ளும் மனநிலையை அடைந்துள்ளேன்

அ. ஆம், எல்லா நேரமும்
ஆ. ஆம், அடிக்கடி
இ. எப்பொழுதாவது
ஈ. இல்லவே இல்லை

Annexure 8: Diagnostic Criteria of Symptoms – Tamil

I அடி வயிற்று வலி
பெண் உறுப்பில் இருந்து அதிகப்படியான நீர் வடிதல்
துர்நாற்றறத்துடன் கூடிய நீர் வடிதல்
பெண் உறுப்பில் நீர் வடியும் போது வலி ஏற்படுதல்

II காய்ச்சல் (குளிர் உணர்வோடு) / காய்ச்சல் குளிர் உணர்வு இல்லாமல்
மார்பக வலி
மார்பகத்தில் வலியுடன் கூடிய கட்டி உள்ளதா ?

III சிறுநீர் கழிக்கும் போது எரிச்சல் ஏற்படுதல்
அடிக்கடி சிறுநீர் கழிக்கும் உணர்வு ஏற்படுதல்
விரைவில் சிறுநீர் கழிக்க வேண்டும் என்ற உணர்வு
காய்ச்சல் (குளிர் உணர்வோடு) / காய்ச்சல் குளிர் உணர்வு இல்லாமல்
அடி வயிற்று வலி

IV காயம் உள்ள இடத்தில்
வலி உணர்வோடு சிவர்ந்து போகுதல் மற்றும் சூடாக இருத்தல்
வீக்கம்
சீவ் வடிதல்

Annexure 9: Institutional Review Board and Ethics committee approval for the research

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho MS Ortho DNB Ortho.
Chairperson, Research Committee & Principal

Dr. Biju George, MBBS., MD., DM
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

June 07, 2016

Dr. [redacted]
PG Registrar,
Department of Community Health,
Christian Medical College,
Vellore 632 004.

Sub: **Fluid Research Funding: New Proposal**
Incidence and risk factors for morbidity among puerperal women in Kaniyambadi block, Vellore- a prospective cohort study.
Dr. Anjali Sriramanarayanan Nair, Emp. No: 21242, PG Registrar, Dr. Kuryan George, Emp. No: 08947, Professor , Dr. Anuradha Rose, Emp. No: 28164, Associate professor, Dr. Anne George Cherian, Emp. No: 28595, Assistant professor, Community Health Department, Dr.Suja Kurian, Emp. No: 30356, Associate professor, Department of Psychiatry

Ref: IRB Min No: 9903 [OBSERVE] dated 05.02.2016

Dear Dr. [redacted]

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY (EC)
Institutional Review Board
Christian Medical College, Vellore - 632 002.

Cc: Dr. Kuryan George , Professor, Department of Community Health, CMC

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

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Ref: IRB Min No: 9903 [OBSERVE] dated 05.02.2016

Dear Dr. [redacted]

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Incidence and risk factors for morbidity among puerperal women in Kaniyambadi block, Vellore- a prospective cohort study" on February 05th 2016.

The Committee reviewed the following documents:

1. IRB Application format
2. Informed Consent Form (English and Tamil)
3. Information Sheet (English)
4. Questionnaire (English and Tamil)
5. EPDS questionnaire
6. Cvs of Drs. Anjali Sriramanarayanan Nair, Anuradha Rose, . Anne George, Suja Kurian, Kuryan George
7. No. of documents 1 - 6

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on February 05th 2016 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002. 2 of 4

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho MS Ortho DNB Ortho.
Chairperson, Research Committee & Principal

Dr. Biju George, MBBS., MD., DM
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC,Vellore	Internal, Clinician
Dr. Nihal Thomas	MD, MNAMS, DNB (Endo), FRACP (Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. CMC, Vellore	Internal, Clinician
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist &Epidemiologist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. Visalakshi. J	MPH, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Niranjan Thomas	DCH, MD, DNB (Paediatrics)	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. B. J. Prashantham	MA(Counseling Psychol MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centr Vellore	External, Social Scientist
Dr. RatnaPrabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Chairperson, Research Committee & Principal

Dr. Biju George, MBBS., MD., DM
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Inian Samarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Incidence and risk factors for morbidity among puerperal women in Kaniyambadi block, Vellore- a prospective cohort study" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in)

Fluid Grant Allocation:

A sum of 83,550/- INR (Rupees Eighty three thousand five hundred and fifty Only) will be granted for 15 months.

Yours sincerely

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS
SECRETARY (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min No: 9903 [OBSERVE] dated 05.02.2016

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